EDQM OMCL

Printout

Online Manual OMCL Database

http://www.edqm.eu/omcldb/

Headquarter

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Online Help - How to use the OMCL Database Manual

Ease of Use

Depending on the way you work, there are different possibilities to find a specific topic or key word.

Sitemap

A menu of sub-pages to the used navigation points is located on every single site in the left column and provides an overview of the topics of the online manual. The complete **sitemap** is provided in the main navigation.

Topics of the online manual are based on the directory of the print manual which has been handed out during the training courses.
Most of the topics / navigation points of the online user manual are explained on single sites where detailed information will be provided.

General Features

General functions applicable for the three domains "OMCL", "Competences" and "User" are summarised in the sub-navigation "**General Features**".

Enlarge Graphics

Graphics will be shown in real-size by clicking on them

Firefox

Please note: The OMCL database is optimised only for the use of the browser Firefox. Please download and install the latest version of Firefox from the Mozilla website at **http://www.mozilla-europe.org** .

How to Access the OMCL Database

Starting Page / Browser Preference

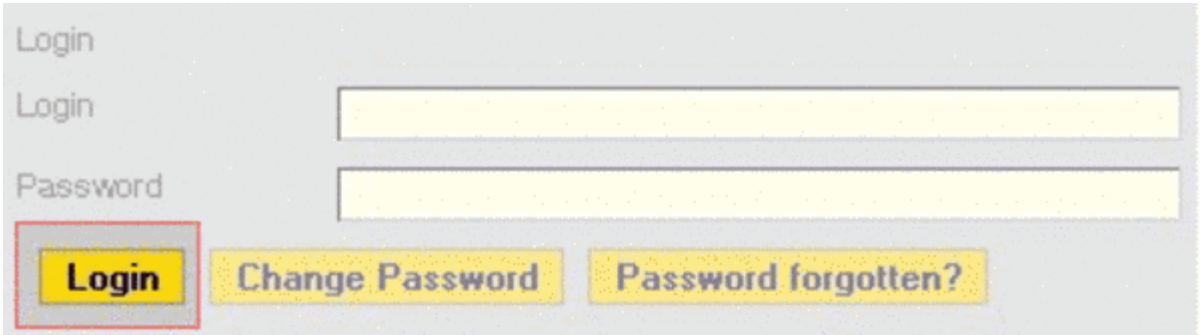
Please open the browser "Firefox" and enter the URL **http://www.edqm.eu/omcldb**. The following screen appears, which is the starting page of the database:

On the starting page you will find a note requesting you to use Firefox as standard browser while working with the database.

Please note: It is very important that Firefox is used, as with any other browser you might not be able to access.

Login Dialogue Box

In order to open the registration dialogue box you have first to activate one of the domains listed in the tool bar. Click e.g. on "OMCL" and the following dialogue box opens:



How to Access the OMCL Database

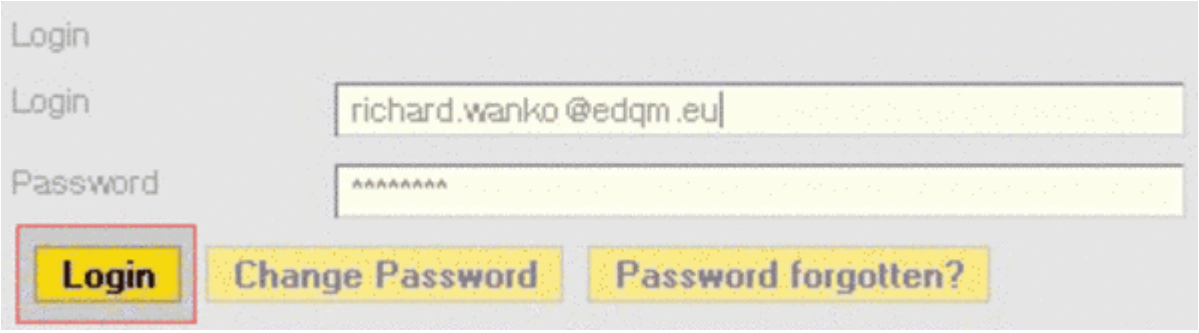
Username / Password

Please enter now your username and password.
Your username is identical to your email address.

Concerning the password please use the one that you have received via the automatic email system (**addresser: omclnet@edqm.eu**).
Below an example on how this automatic email looks like is provided.

Receipt of new password — europarat
E-Mail(s) löschen
Ist Werbung
Antworten
An alle
Weiterleiten
Drucken
Von: Richard Wanko
Betreff: Receipt of new password
Datum: 28. Februar 2007 22:05:01 GMT+01:00
An: Björn Senti
Antwort an: Richard Wanko
Please find enclosed your new password to be used to access the OMCL inventory database.
Your password reads as follows: Qqsc8f24
You can modify your password by using the "Change password" function.

Please note that the **username** is not case sensitive. You can use capital or small letters and the system will identify the "username" = "email address" correctly.
On contrary the **password** is case sensitive. So please respect capital and small letters in the password you have received via email.
In order to avoid typing errors it is recommended to simply copy and paste the password from your email to the password field.



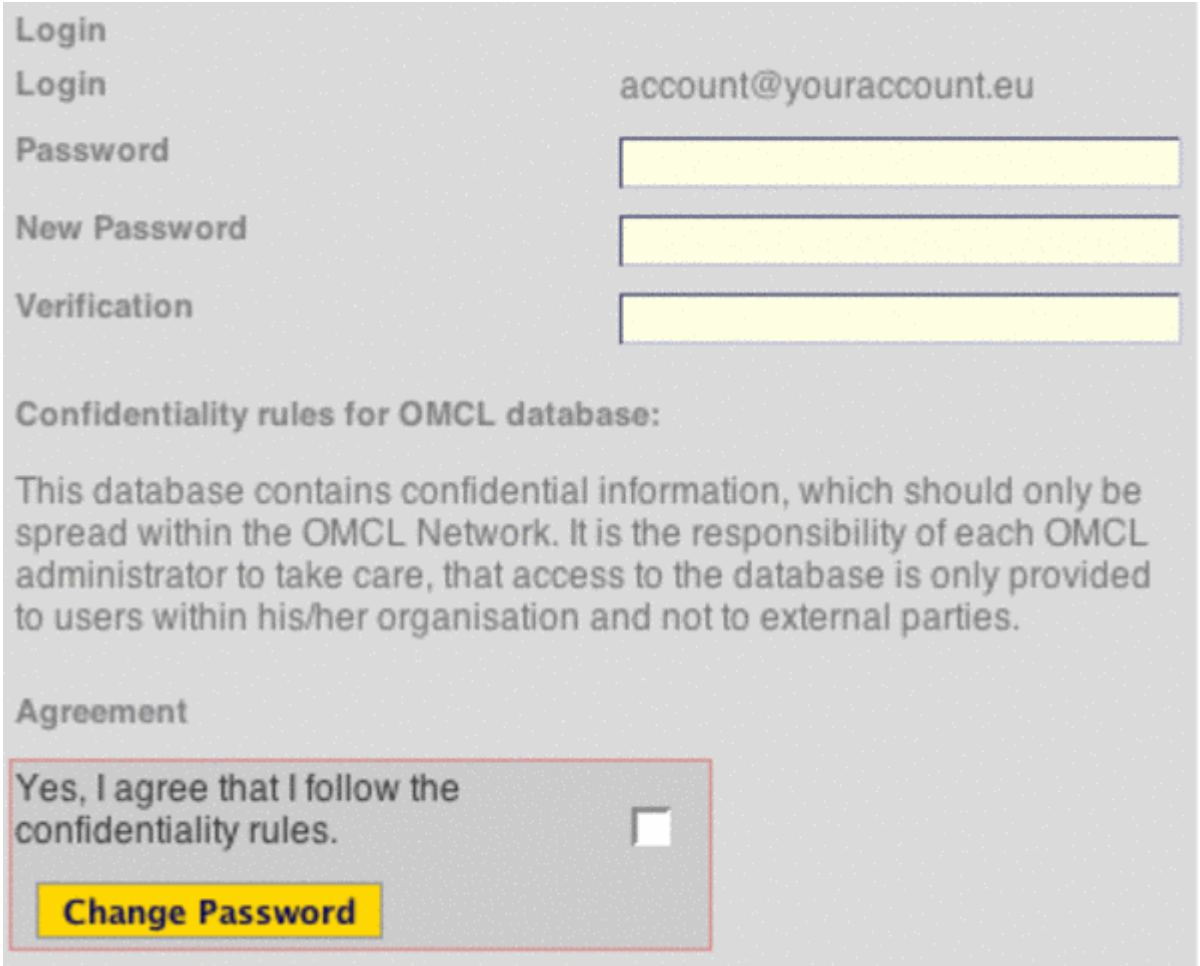
How to Access the OMCL Database

Changing the Password

When logging-in with the password that was provided to you by the automatic email, a new dialogue box will open automatically with the request to change your password immediately. In the first field ("Password") you have now to enter the old password once again, while in the next two fields ("New Password" and "Verification") you enter twice a new password of you own choice. You can select any password.

For security reasons it is recommended to choose a password with at least 6 characters. Your password doesn't need to be a combination of letters and figures, although this would make it saver; in any case please don't forget that also your new password is case sensitive.

Before validating the new entries by activating the "Change Password" button you have to activate the tick-box next to the Agreement declaration. Please read first the "Confidentiality rules for OMCL database" before clicking the box.


Login
Login
account@youraccount.eu
Password
New Password
Verification
Confidentiality rules for OMCL database:
This database contains confidential information, which should only be spread within the OMCL Network. It is the responsibility of each OMCL administrator to take care, that access to the database is only provided to users within his/her organisation and not to external parties.
Agreement
Yes, I agree that I follow the confidentiality rules.
Change Password

By clicking on the "Change Password" button you have finally entered the database and can now work within the IT application. An automatic email will be sent to your address confirming that your password has been changed successfully.

Receipt of confirmation of password change — storm
E-Mail(s) löschen
Ist Werbung
Antworten
An alle
Weiterleiten
Drucken
Von: omclnet@edqm.eu
Betreff: Receipt of confirmation of password change
Datum: 11. Juni 2007 18:17:21 GMT+02:00
An: Björn Senti
Antwort an: omclnet@edqm.eu
Please be informed that your password to access the OMCL inventory database has been changed successfully.

How to Access the OMCL Database

Errors while changing Password

If you have made a mistake - e.g.:

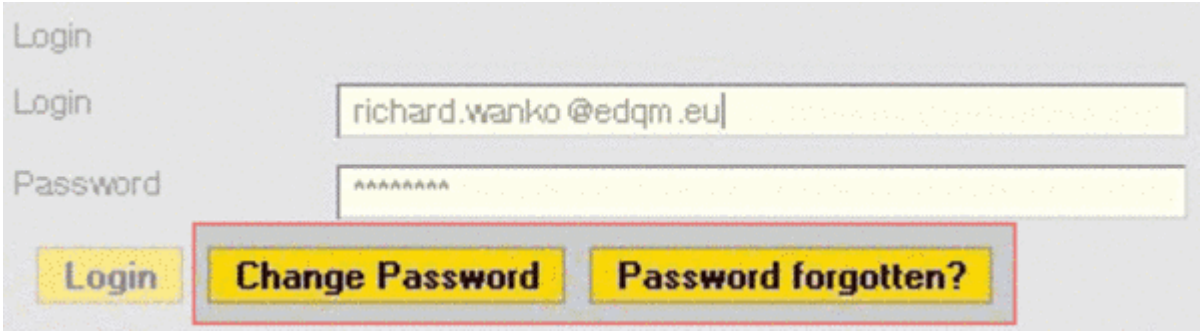
- use of wrong old password,
- the two fields "New Password" and "Verification" do not match,
- you have forgotten to activate the tick-box,
- the combination username and new password was already used earlier for this computer application etc.

you will receive an automatic message asking you to take corrective actions.

In case you wish to change your password at a later time point again, you can do so whenever you enter the database by clicking on the respective button "Change Password".

Password forgotten

If you have forgotten your password a new one can be sent to you by automatic email. For this purpose you have to enter your username in the login field and click on the button "Password forgotten?". You will receive an automatic message on the top end of the dialogue box informing you that "A new password has been sent to your email address".



How to Access the OMCL Database

Log-Out

Please note: If you do not use the database for longer than 30min, the system will logout automatically and you will be asked to re-enter your username and password again, after you re-start working with the database.
You can actively log-out by clicking on the "Logout" button, which you find on the right hand side of the "domain tool bar" of the starting page.

Navigation

What are the main domains and folders you will work with as an OMCL User?

On the top level navigation of all database screens you find a tool bar including a number of features:

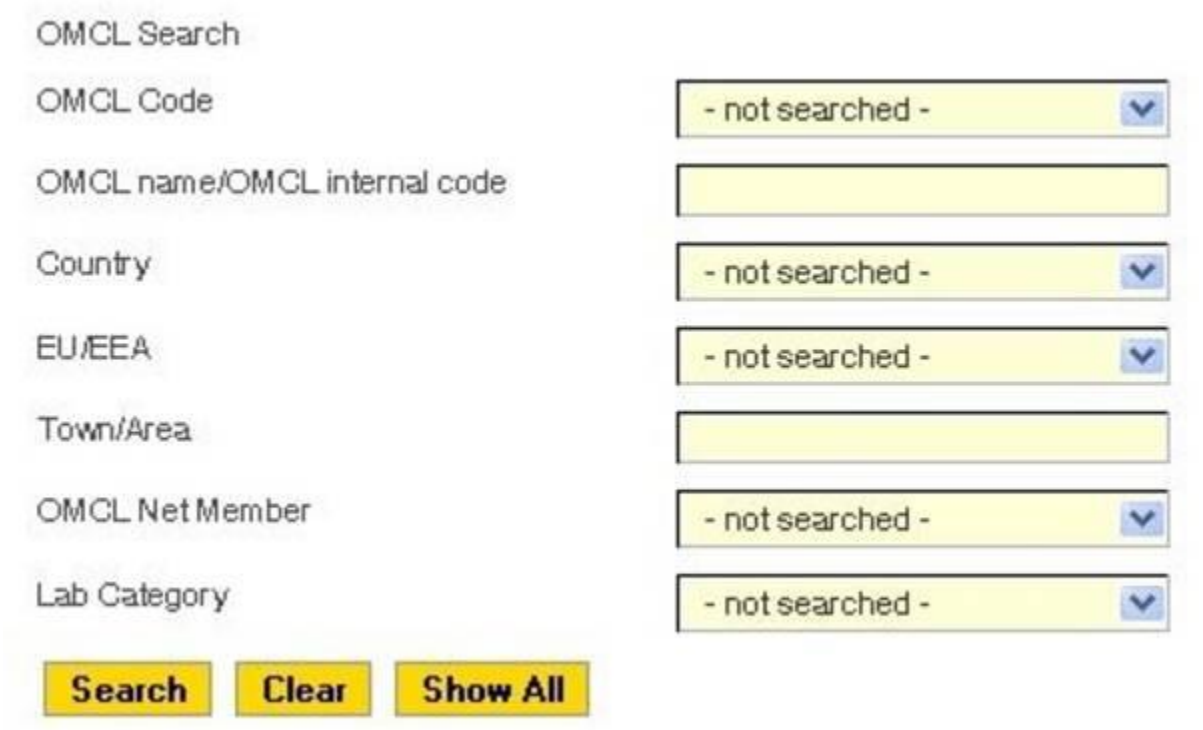
Top Level Navigation / Domain Tool Bar

- **Home**
  With the button "Home" you can at any time go back to the starting page.
- **OMCL**
  The button "OMCL" allows you to access the general information about the OMCLs of the Network.
- **Competences**
  The button "Competences" leads you to detailed information about the testing activities of the member of the OMCL Network.
- **User**
  In the domain "User" you can define access rights (admin, read/ write or read only) for all OMCL users within your organisation.
- **Logout**
  The "Logout" button is the recommended way how to leave the database.
- **Help**
  The "Help" section includes a comprehensive description of the database.
  In the upper left corner of www.edqm.eu/omcldb online help is provided. The question mark leads you to the respective information.

- **Mail Support**
  Finally questions, which cannot be found in the user manual/help section, can be sent to the following general email address: **omclnet@edqm.eu** and will be treated by the DBO colleagues dedicated to this database project.

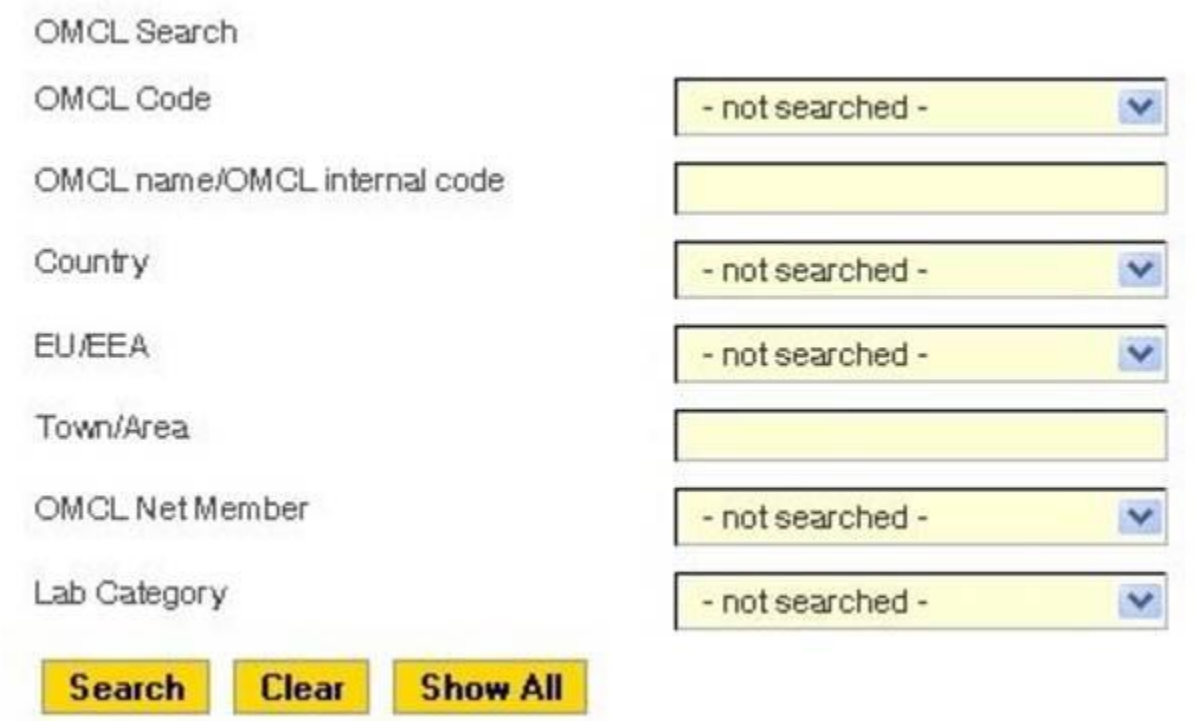
The OMCL Domain

When clicking on "OMCL" a search dialogue box opens.



The OMCL Domain

Search Functions - Search Dialogue Box within OMCL domain



With the help of the search dialogue box you can narrow your search either by selecting from a pop-up menu (applicable for all fields which have an "Arrow" button on the right hand side), or by entering a text in an empty field.

Please note: The searches in a free text field are "wild card" searches. This means, that you can search for the OMCL name "Austrian Medicines Agency" by entering "Austr Med" or "Austr Ag" but not by entering "Ag Aust", as the sequence of the words has to be adhered.

- **Search Field within OMCLs**
  The search field "OMCL name/OMCL internal code" covers the two fields "OMCL Name" and "OMCL internal Code"; the search field "Town/Area" covers the fields "Area" and "Town". It should be noted that entered text must not include text elements from both fields, as the set-up for searches does not combine texts from different fields, but must only include elements from one of the two fields in order to get a positive result.

- **Activating a Search Button for OMCL (Search Button)**
  In order to initiate a search the "Search" button has to be activated.

- **Clearing Search for OMCL**
  You can delete all search options simply by clicking on the "Clear" button or by deleting them manually step-by-step.

- **OMCL List**
  In case you want to see the complete list of OMCLs please click on "Show All". You will obtain the same result by leaving all search fields empty and activating the "Search" button.

This will lead you to the following list.

OMCL 67/67

OMCL Code	OMCL Name	Country	Town	OMCL Net Member	
OMCL-AT_AGES-B	Austrian Medicines Agency	Austria	Vienna	Full member	Open
OMCL-AT_AGES-C	Austrian Medicines Agency	Austria	Vienna	Full member	Open
OMCL-AU_TGAL	Therapeutic Goods Administration Laboratories	Australia	Canberra	Associated	Open
OMCL-BA_IMQC	Institute for Medicines Quality Control	Bosnia Herzogovina	Sarajevo	Full member	Open
OMCL-BE_IPH-B	Scientific Institute Public Health – Section Biological Standardisation	Belgium	Brussels	Full member	Open
OMCL-BE_IPH-C	Scientific Institute of Public Health, Medicines Section	Belgium	Brussels	Full member	Open
OMCL-BE_VAR	Veterinary and Agrochemical Research Center	Belgium	Ukkel	Full member	Open
OMCL-BG_BDA	Bulgarian Drug Agency	Bulgaria	Sofia	Full member	Open
OMCL-BG_ICVP	National Veterinary Service, Institute for Control of Veterinary Medicinal Produ	Bulgaria	Sofia	Full member	Open
OMCL-CA_BGTD	Biologics and Genetic Therapies Directorate	Canada	Ottawa	Associated	Open

The list can be selected in ascending or descending alphabetic order by clicking on the respective arrows next to the column titles. In the upper left corner you get information about the number of records available within this domain (same is applicable also for the Competences and User domains).

The OMCL Domain

OMCL detailed Information / Deletion of OMCL records

OMCL 67/67

OMCL Code	OMCL Name	Country	Town	OMCL Net Member	
OMCL-AT_AGES-B	Austrian Medicines Agency	Austria	Vienna	Full member	Open
OMCL-AT_AGES-C	Austrian Medicines Agency	Austria	Vienna	Full member	Open
OMCL-AU_TGAL	Therapeutic Goods Administration Laboratories	Australia	Canberra	Associated	Open
OMCL-BA_IMQC	Institute for Medicines Quality Control	Bosnia Herzogovina	Sarajevo	Full member	Open
OMCL-BE_IPH-B	Scientific Institute Public Health – Section Biological Standardisation	Belgium	Brussels	Full member	Open
OMCL-BE_IPH-C	Scientific Institute of Public Health, Medicines Section	Belgium	Brussels	Full member	Open
OMCL-BE_VAR	Veterinary and Agrochemical Research Center	Belgium	Ukkel	Full member	Open
OMCL-BG_BDA	Bulgarian Drug Agency	Bulgaria	Sofia	Full member	Open
OMCL-BG_ICVP	National Veterinary Service, Institute for Control of Veterinary Medicinal Produ	Bulgaria	Sofia	Full member	Open
OMCL-CA_BGTD	Biologics and Genetic Therapies Directorate	Canada	Ottawa	Associated	Open

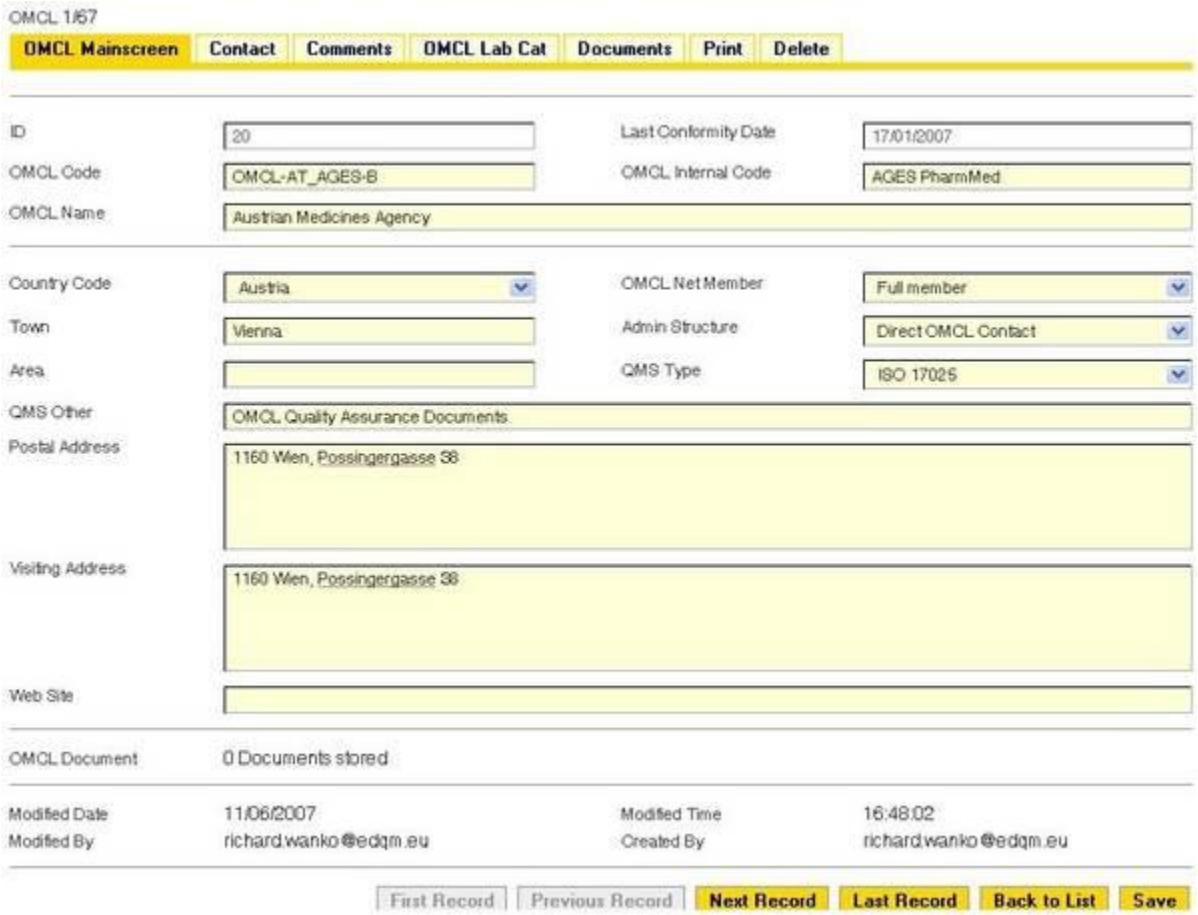
You can click on any "Open" button to access to detailed information concerning the respective OMCL. You are not allowed to delete any OMCL record (on your screen there does not appear a "Delete" button). In case you click on the "Open" button of your OMCL, you are allowed to change data within your own records.

The example in the next section "OMCL Domain/Overview" shows, what an OMCL read/write user from the OMCL "AT_AGES-B" can do, when opening his/her own records.

The OMCL Domain

Records Structure - Detailed Records of OMCLs (Sub Navigation)

After clicking on "Open" the main detail screen of the OMCL AT_AGES-B opens.



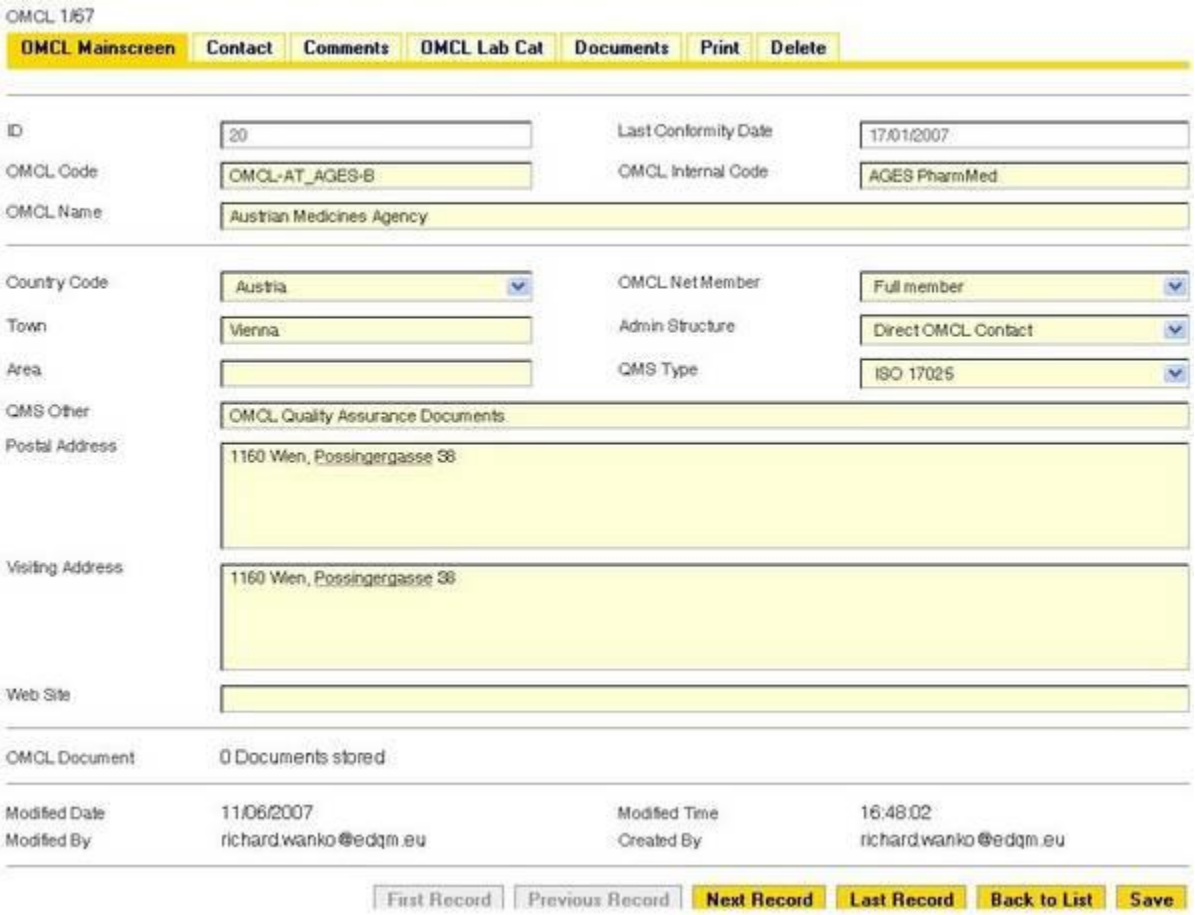
Navigation Rider

Please have a look at the riders' bar on top of this screen, which allows you to switch between different sub-sections/folders. They are defined as follows:

- **OMCL Mainscreen**
  Provides general information about the OMCL.
- **Contact**
  Provides information about OMCL and QA contacts.
- **Comments**
  This page allows you to add free text related to different activities of your OMCL.
- **OMCL Lab Cat**
  Provides information on the type of laboratories available within the OMCL.
- **Documents**
  In this folder uploaded documents related to the respective OMCL can be found and downloaded; within your own OMCL record you can upload new documents (e.g. annual reports).
- **Print**
  In this folder you have the possibility to print available information related to the respective OMCL in a predefined format. Please note that Firefox allows you to print any page of the database, if so wished.
- **Delete**
  Via this folder a complete OMCL record can be deleted; you are not allowed to delete any OMCL record, not even your own record, this can only be done by the EDQM system administrators.

The OMCL Domain

Saving Information



Please note: In case you switch between folders within the OMCL domain (also applicable for the Competences domain) all data, which have been added or changed in the folder you have just left, will get lost, if you forget to click the "Save" button. This is not applicable for information added, modified or deleted with an "Add record" / "Edit record" and "Delete" button.

In order to go back from the detailed folders to the OMCL list, please use the "Back to List" button. The same principle also applies for the OMCL and User domain.

Switching between Records

On the bottom end of each screen you find in addition buttons, which allow you to switch between different records from a selected list. You can switch between the corresponding folders of each record by using the "First Record", "Previous Record", "Next Record" and "Last Record" button; the same principle is also valid for the OMCL and User domain.

Information about Modification

In addition you will find at the bottom end of each folder information about the last data modification date, the last modification time and an identifier (email address) of the person, who created the complete OMCL record and who modified existing data within a record the last time; this also applies to the Competence and User domain.

The number of documents attributed to an OMCL record is provided on each folder of the OMCL domain.

Position of Record

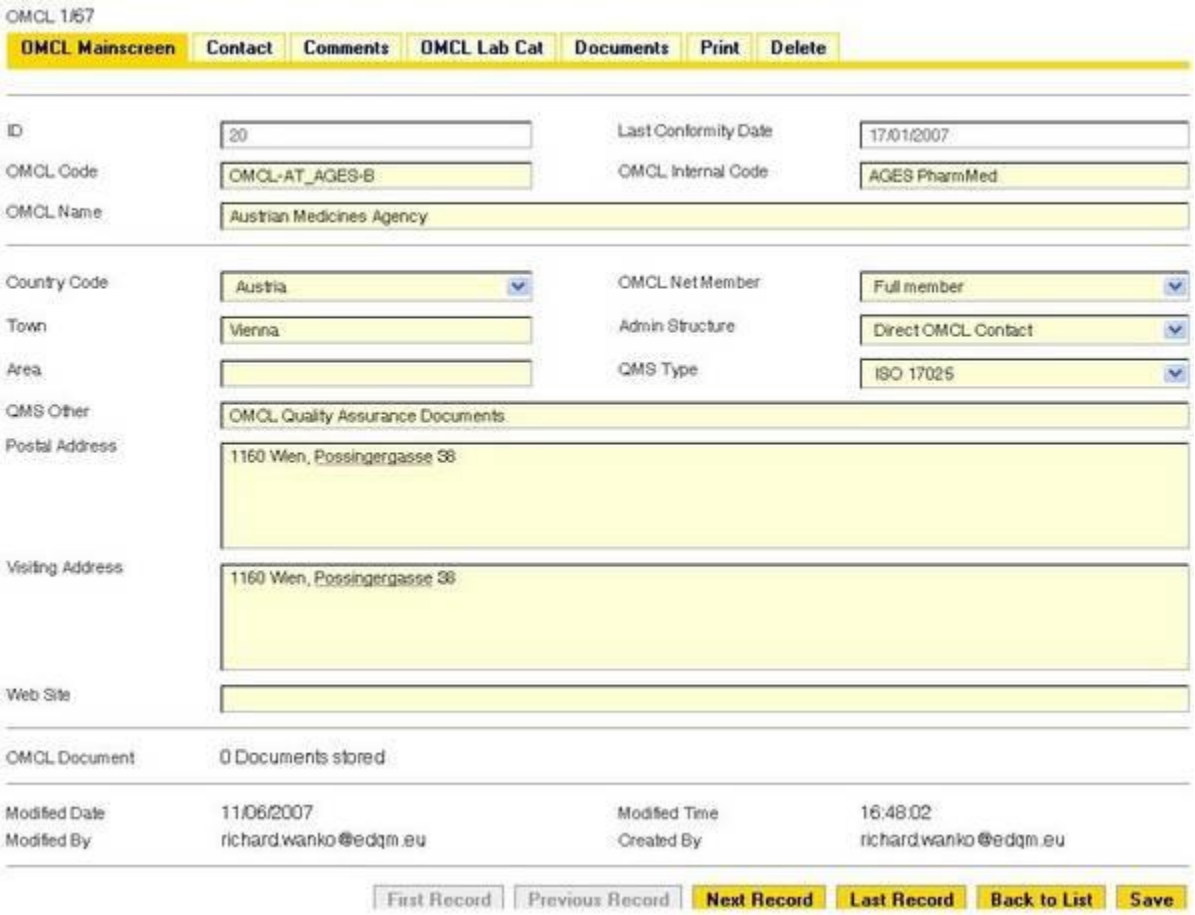
Finally in the upper left corner of the screen you find information about the position of the record within the respective domain. In the example given below you are under domain OMCL in the first out of 67 OMCL records in the folder OMCL Mainscreen. The same applies for the domains Competences and Users.

In the next sections you find the screen shots of all above-mentioned sub-section/folders providing detailed information about their content and their functionality.

The OMCL Domain

OMCL Mainscreen Screenshot

The OMCL main screen has the following structure



Working within your own OMCL Domain

If you enter your own OMCL record, you will be allowed to change any data within this record with the exception of "ID" (identity code provided automatically by the system), the "OMCL code" (can be changed by the EDQM system administrator only upon request) and "Last Conformity Date" (triggered by the conformity procedure described in the respective section).

In the field "OMCL Internal Code" you can add the code, which is used within your organisation to identify your OMCL; this code might also form part of in the official "OMCL code", e.g. INFARMED, NAM etc.

The field "Admin Structure" provides information, whether the contact point of an OMCL is directly located at the OMCL level (Direct OMCL Contact), or communication runs via the corresponding authority (Central Authority Contact), which is the case in some few member states.

The membership terms "full member" and "associated member" follow the present definition of the GEON Terms of Reference.

The fields "QMS Type" and "QMS Other" should provide information about the Quality Management System, which is in place at the OMCL. The first reference should preferably be "ISO 17025". Other standards can be quoted in the text field "QMS Other".

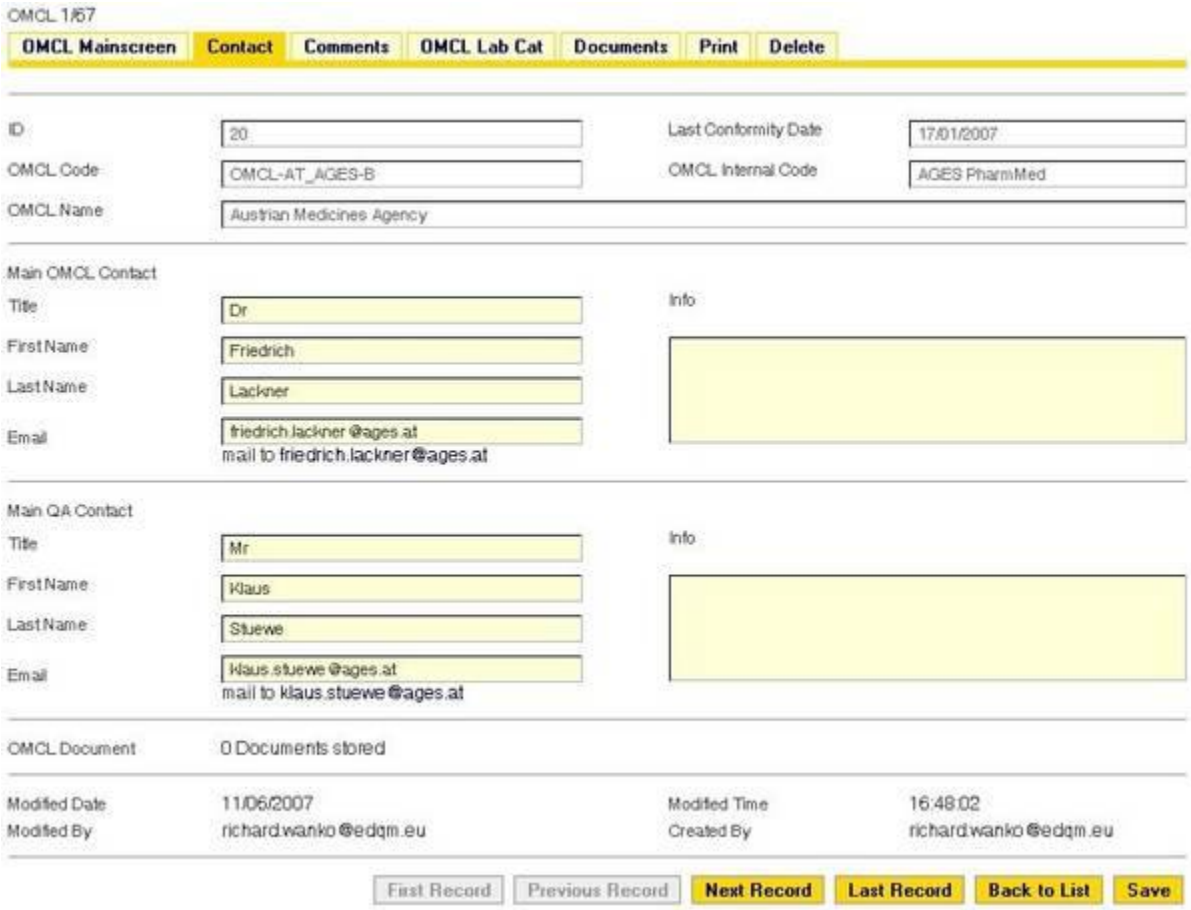
Provided that you have added an URL address for your organisation, a link will be established, which leads users automatically to the corresponding web site.

In case you are updating information in this screen don't forget to save them by clicking on the "Save" button.

The OMCL Domain

Contact Screenshot

The Contact main screen has the following structure



Contact Details

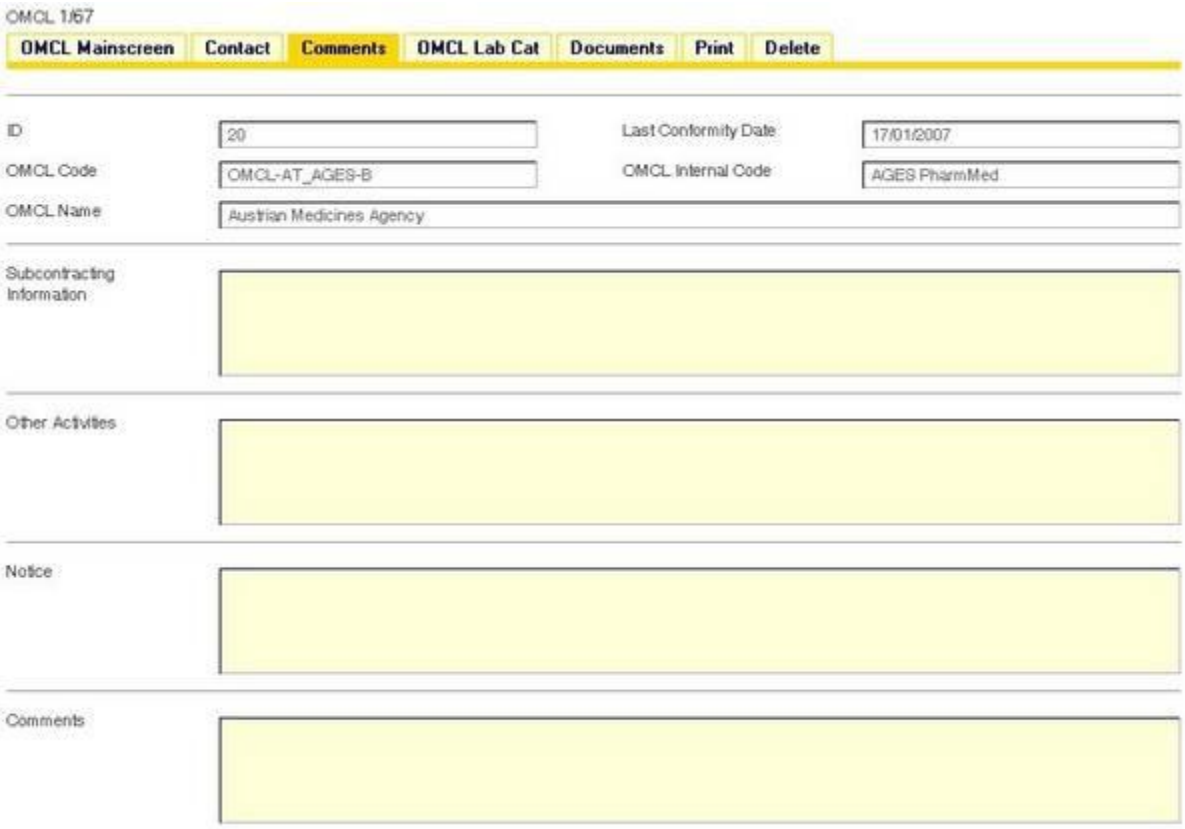
Your main contact person for the OMCL and QA activities are added in the respective fields under this sub-section. The attached email links will automatically open your mailing system (link has to be established once on your computer) and you can write immediately an email to the respective address. In the free-text fields of the section you can add additional information, e.g. about another contact point, a general email address etc.

In case you change data and forget to click the "Save" button, they will get lost as soon as you switch to another folder.

The OMCL Domain

Comments Screenshot

The Comments main screen has the following structure



Additional Information under Comment Folder

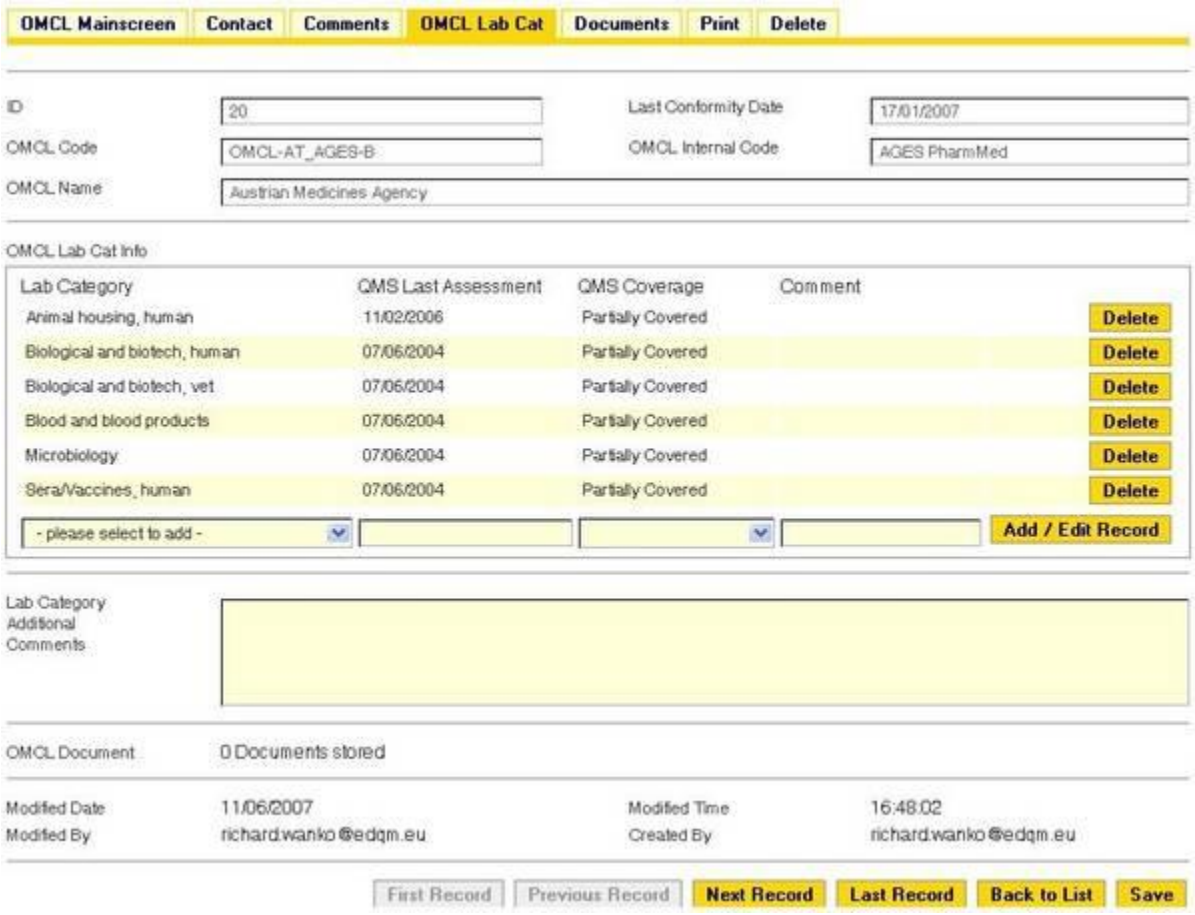
The comments folder provides you with a variety of possibilities for adding information. For any activities, which you are subcontracting, and for other activities (e.g. research, development) you can use the respective fields to give additional information.
The text field notice should be reserved for quick information exchange (e.g. the temporary shut down of a lab due to reconstruction works etc.).
Finally the field comments is reserved for other general information related to your OMCL (e.g. organisational items of general interest, information about LIMS etc.).
If the text fields will be used frequently by OMCLs during the next couple of years to share information it might be envisaged to define some more standardised fields in the next version of the database.

In case you change data please don't forget to click on the "Save" button.

The OMCL Domain

OMCL Lab Cat Screenshot

The OMCL Lab Cat main screen has the following structure



Additional Information

In the lab category folder you find detailed information about the lab categories/types of laboratories available within the respective OMCL.

Adding / Editing Records

Please note: In case of adding a new lab category or changing an existing record, by clicking on "Add / Edit Record" you have already saved the changes. You don't need to click the save button: again this is only necessary when entering text or making changes in the comment field "Lab Category Additional Comments".

Update Existing Data

If you want to update already existing data of a lab category, please select the corresponding lab category again from the pop-up list and edit the corresponding fields. For entering a date in the field "QMS last assessment" any "European convention" using only figures for expressing a date (e.g. "12.11.04", "12/11/06") will produce the result "12/11/2006". By clicking on "Add / Edit Record" the old set of data will be overwritten automatically.

Concerning the fields "QMS last assessment" this should address the date of the last external assessment of your QMS against the standard ISO 17025 and respective OMCL guidelines either in course of an MJA (starting from an initial "MJA" upwards) or by another comparable external audit program.
Alternatively the QMS of the lab categories is considered as externally assessed, if it is covered by the scope of accreditation document issued issues by a competent accreditation body.
Please put as date either the issue date of the MJA attestation (if not available the last date of the MJA itself) or the "valid from" date stated on the accreditation certificate.
Dependent on the scope of accreditation or the scope of the MJA, within the lab category all methods ("all covered"), only parts of the methods ("partially covered") or no methods might be QMS covered. In the latter case this field should remain empty.

In the comment box next to the lab category you can add additional information related to the QMS coverage of the respective lab category.

Comment Boxes under OMCL Lab Cat Folder

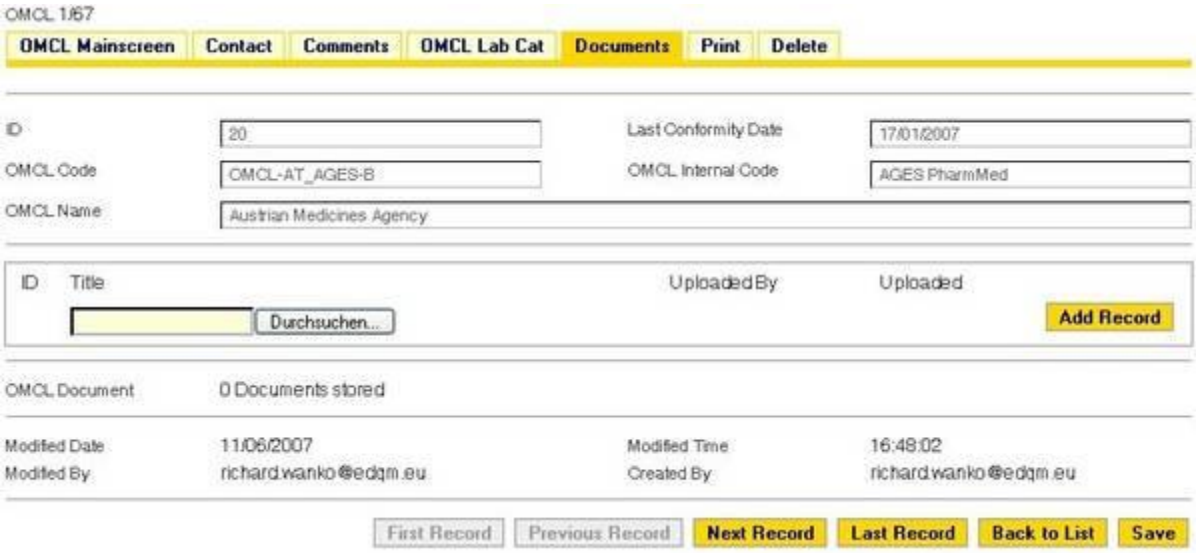
In case of a blank MJA, an MJV or a tutorial you can add this piece of information in the corresponding specific comment fields or in the general comment field "Lab Category Additional Information". In that case the "QMS coverage" field must remain empty.

In the general comment box on the bottom end of the folder you can also provide additional information about any of your lab categories e.g. your intention to open a new type of lab in the near future.

The OMCL Domain

Documents Screenshot

The Documents main screen has the following structure

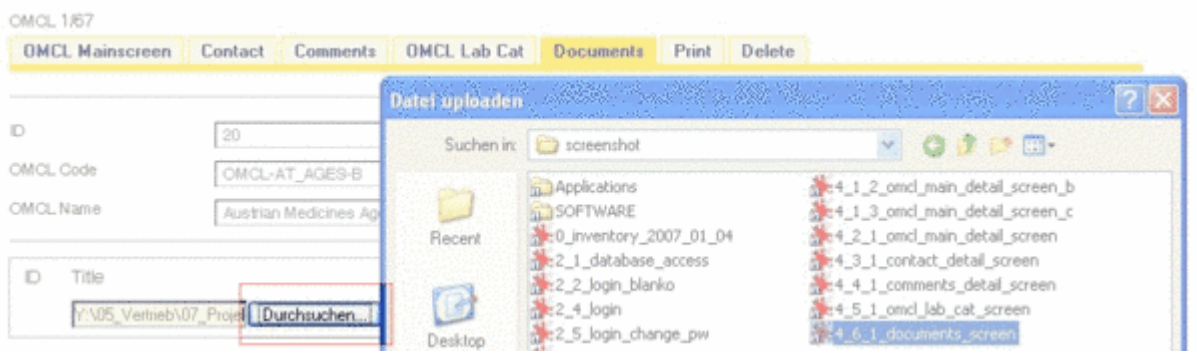


In this sub-folder you can upload any kind of documents (.doc, .xls, .pdf, .jpg etc.) or can download documents stored by other OMCLs in their records.

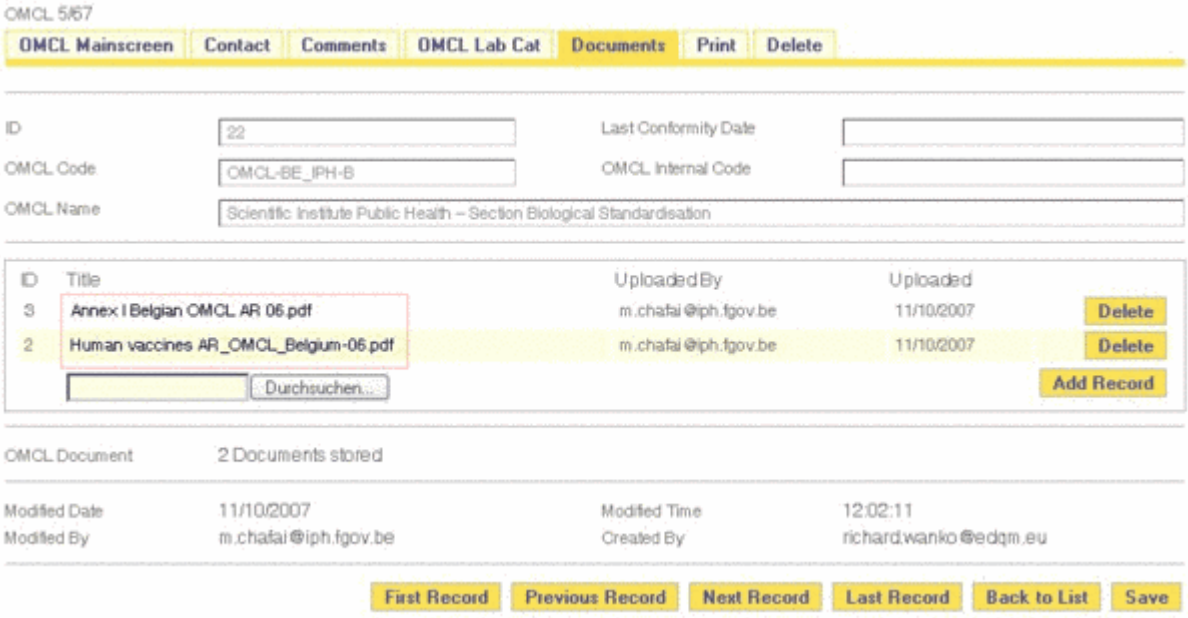
Uploading a Document

In order to upload a document you first browse within your computer (click on the "Browse…" button), open the respective file and then activate the "Add Record" button.

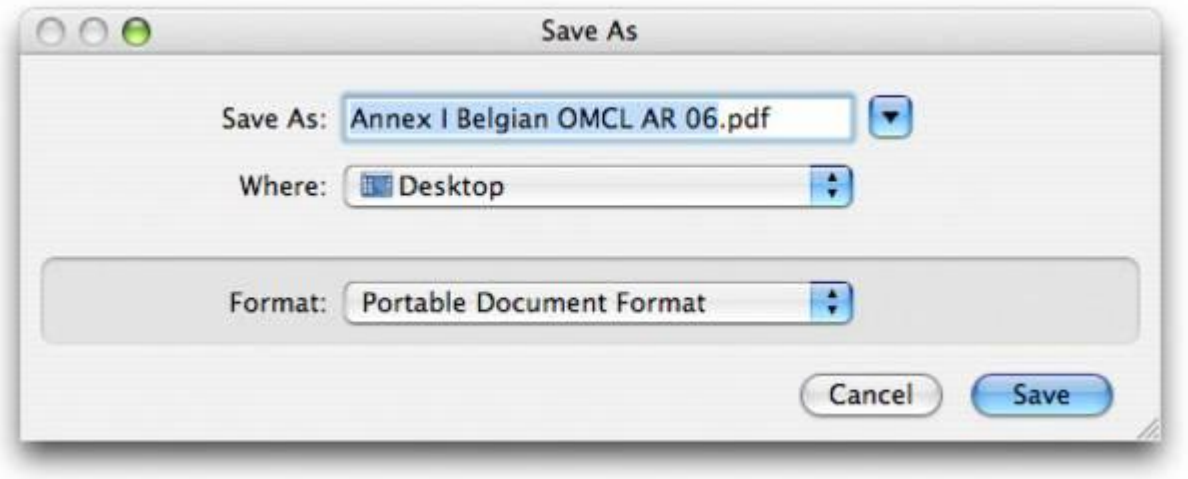
Please note: By clicking on "Add Record" the document will already be saved.



Downloading a Document



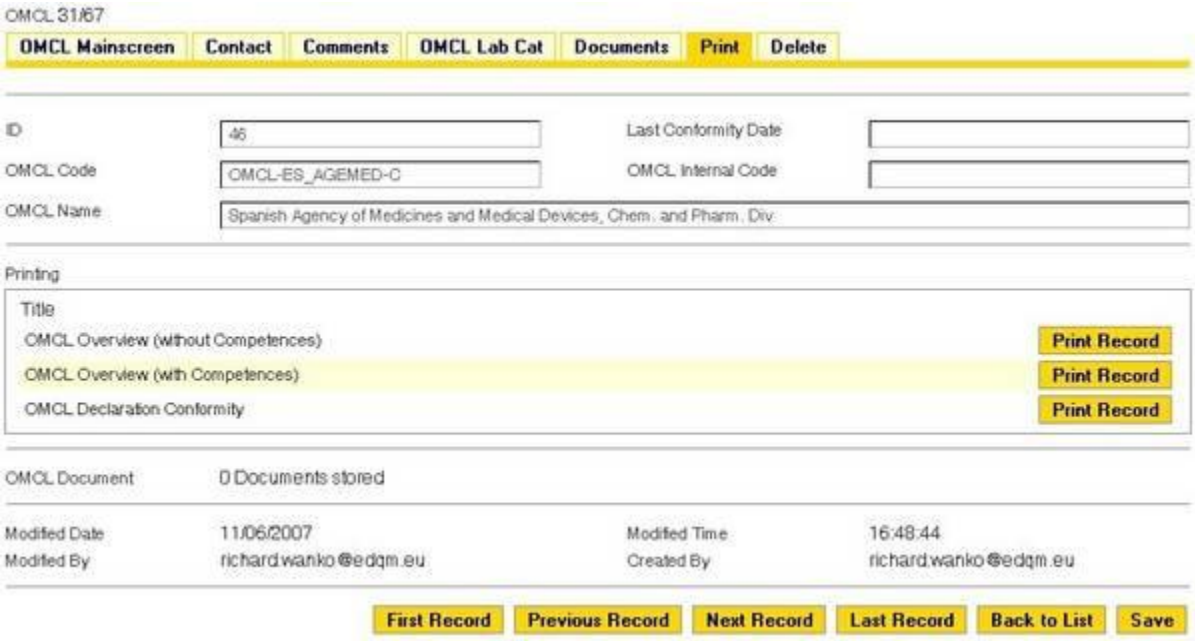
In order to download a document simply click on the document title and your computer will give you further instructions how to save the file e.g. on your desktop.



The OMCL Domain

Print Screenshot

The Print main screen has the following structure



Print Options

There are three standardised print options. Each OMCL can print its own record and the records of all other OMCLs inclusively or exclusively the corresponding competences by activating the respective print button. In addition only the concerned OMCL can print its own OMCL Declaration Conformity Document, which it has to sign and send back to EDQM.

With this declaration the OMCL confirms, that all data of the database are up-to-date. An official request to send this declaration will be made on a yearly basis by EDQM.

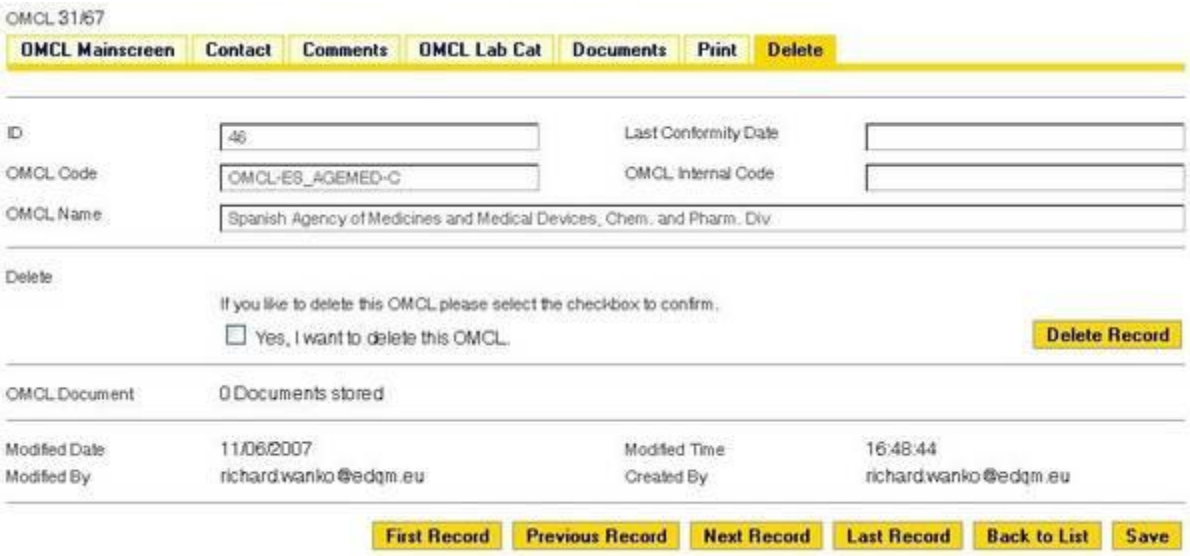
Please note: The list of competences is sub-divided in three categories: physicochemical tests, biological tests involving animals and biological tests not involving animals. The test methods in the standard prints are sorted within these three categories in alphabetic order. This should allow an easier distribution of the prints within the OMCL e.g. for a data validity check.

The OMCL Domain

Delete Screenshot

Screen from a non-authorised users.

Delete complete OMCL Record



The delete sub-section allows authorised users (EDQM system administrator) to delete a complete OMCL record. Before the "Delete Record" button can be activated, the box "Yes, I want to delete this OMCL" needs to be ticked.

OMCLs user cannot access the "Delete" folder (folder is marked in grey) and thus are not authorised to delete complete OMCL records, not even their own set of data.

The Competences Domain

When clicking on "Competences" again a search dialogue box opens.
This is definitively one of the key functions of the database. It allows you to search for competences available within the network.

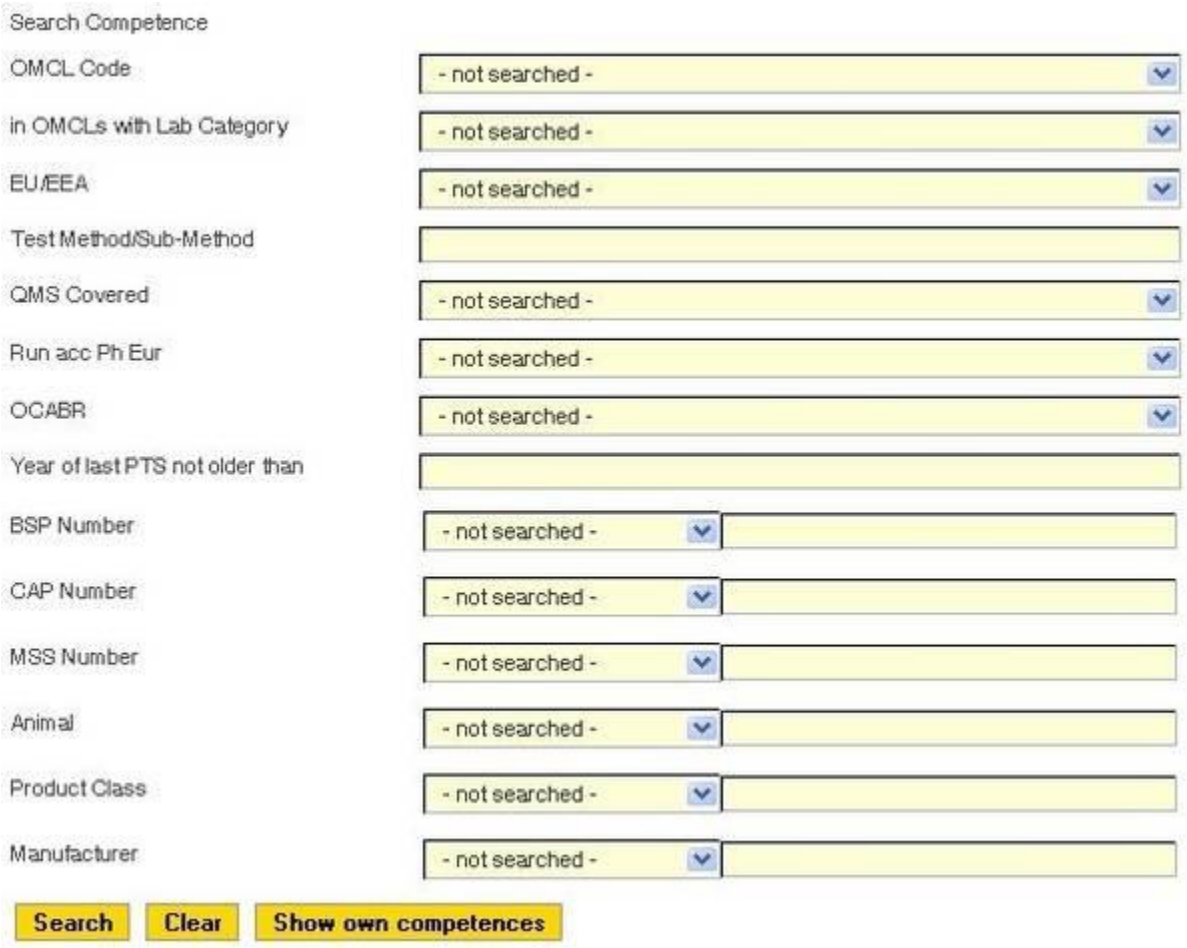
Search Competence

OMCL Code	- not searched -
in OMCLs with Lab Category	- not searched -
EU/EEA	- not searched -
Test Method/Sub-Method	
QMS Covered	- not searched -
Run acc Ph Eur	- not searched -
OCABR	- not searched -
Year of last PTS not older than	
BSP Number	- not searched -
CAP Number	- not searched -
MSS Number	- not searched -
Animal	- not searched -
Product Class	- not searched -
Manufacturer	- not searched -

Search Clear Show own competences

The Competences Domain

General Search Fields
Search Dialogue Box within Competence Domain



Clearing a Search for Competence

In order to start a new search you can click on the button "Clear", which will clear all search fields including data from a previous search. Of course data can also be deleted manually step-by-step by manipulating the fields individually.

Search for own competence

If you enter your OMCL code into the "OMCL Code" search field and then activate the "Search" button, while keeping all other fields blank, you will get a list of all competences related to your OMCL. The same is applicable when you activate the button "Show own competences".

"Pre-Selection Search" for Competences

In a number of fields you can make pre-selections by choosing from a pop-up menu (applicable for all fields with an "arrow" symbol on the right hand side).

Search for Test Method / Sub-Method

In the field "Test Method/Sub-Method" you can enter a combination of words (or part

of words) and the system will search within the test method and the sub-method fields for combined hits similar to a "Google search";

Please note: The search under "Competences" allows more flexibility in comparison to the wild card search described under "OMCL".

Search for PTS Information

For a "Year of last PTS not older than" search you add a year code (e.g. "2005" or "05") and all competences with attributed PTSs performed in 2005 or later will be displayed in a list.

The Competences Domain

Search in Combined Search Fields

At the bottom end of the search screen you find a number of search fields, which allow a combination of pop-up menu and free text search.

You can either make a general search for competences, which are e.g. allocated to the CAP program (or the opposite - all competences not allocated to the CAP program):

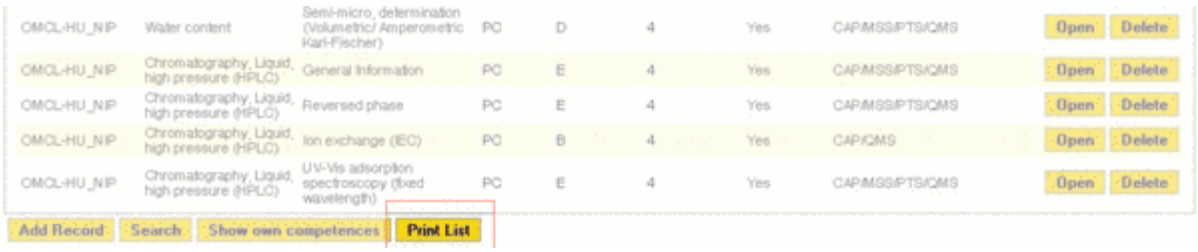
or you can specify a particular CAP program by entering either the CAP number (or parts of the CAP number) or the name of the related study.
A combination of CAP number and study name in one step is not possible.

When adding a text in the free text fields please make sure that the corresponding pop-up field is either put on "not searched" or "yes". The same search principle applies to all other searches employing the combined search fields (e.g. for BSP, MSS).

Limitation of Combined Searches
Please note: There is no link between OMCL, lab category and test method. That means by choosing an OMCL and a lab category you will not end up in a list of all competences within a lab category of the selected OMCL. This was done on purpose as otherwise the structure of the database would have become too complex and inflexible.
The "Lab Category" search in combination with a defined "test method" will instead result in a list of all OMCLs performing this test method, which have in addition the respective lab category available within their organisation; this search could make sense e.g. if you look for a biological orientated lab performing HPLC.

Print List

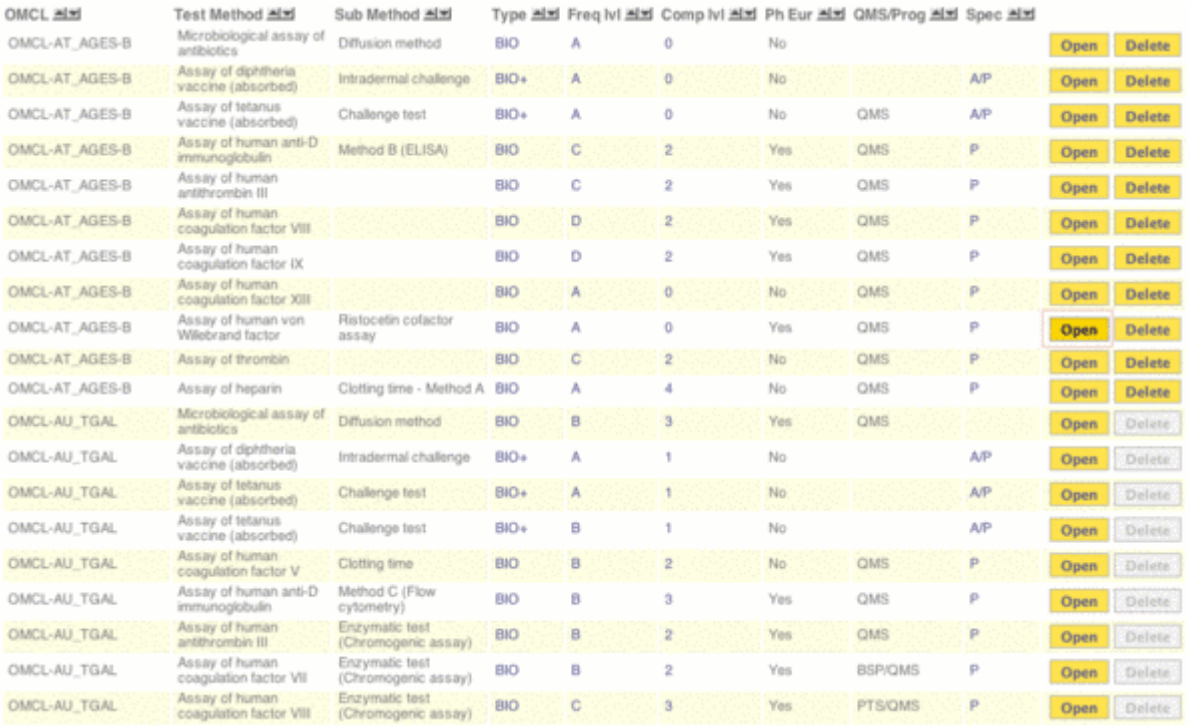
You can print the short list of a search result in a standardised format by clicking on the button "Print List", which is located on the bottom end of the competence list.



The Competences Domain

Competence Overview

If you clear all search fields and click on "Search" you come to the complete list of all competences sorted per OMCL.



OMCL	Test Method	Sub Method	Type	Freq lvl	Comp lvl	Ph Eur	QMS/Prog	Spec		
OMCL-AT_AGES-B	Microbiological assay of antibiotics	Diffusion method	BIO	A	0	No			Open	Delete
OMCL-AT_AGES-B	Assay of diphtheria vaccine (absorbed)	Intradermal challenge	BIO+	A	0	No		A/P	Open	Delete
OMCL-AT_AGES-B	Assay of tetanus vaccine (absorbed)	Challenge test	BIO+	A	0	No	QMS	A/P	Open	Delete
OMCL-AT_AGES-B	Assay of human anti-D immunoglobulin	Method B (ELISA)	BIO	C	2	Yes	QMS	P	Open	Delete
OMCL-AT_AGES-B	Assay of human antithrombin III		BIO	C	2	Yes	QMS	P	Open	Delete
OMCL-AT_AGES-B	Assay of human coagulation factor VIII		BIO	D	2	Yes	QMS	P	Open	Delete
OMCL-AT_AGES-B	Assay of human coagulation factor IX		BIO	D	2	Yes	QMS	P	Open	Delete
OMCL-AT_AGES-B	Assay of human coagulation factor XIII		BIO	A	0	No	QMS	P	Open	Delete
OMCL-AT_AGES-B	Assay of human von Willebrand factor	Ristocetin cofactor assay	BIO	A	0	Yes	QMS	P	Open	Delete
OMCL-AT_AGES-B	Assay of thrombin		BIO	C	2	No	QMS	P	Open	Delete
OMCL-AT_AGES-B	Assay of heparin	Clotting time - Method A	BIO	A	4	No	QMS	P	Open	Delete
OMCL-AU_TGAL	Microbiological assay of antibiotics	Diffusion method	BIO	B	3	Yes	QMS		Open	Delete
OMCL-AU_TGAL	Assay of diphtheria vaccine (absorbed)	Intradermal challenge	BIO+	A	1	No		A/P	Open	Delete
OMCL-AU_TGAL	Assay of tetanus vaccine (absorbed)	Challenge test	BIO+	A	1	No		A/P	Open	Delete
OMCL-AU_TGAL	Assay of tetanus vaccine (absorbed)	Challenge test	BIO+	B	1	No		A/P	Open	Delete
OMCL-AU_TGAL	Assay of human coagulation factor V	Clotting time	BIO	B	2	No	QMS	P	Open	Delete
OMCL-AU_TGAL	Assay of human anti-D immunoglobulin	Method C (Flow cytometry)	BIO	B	3	Yes	QMS	P	Open	Delete
OMCL-AU_TGAL	Assay of human antithrombin III	Enzymatic test (Chromogenic assay)	BIO	B	2	Yes	QMS	P	Open	Delete
OMCL-AU_TGAL	Assay of human coagulation factor VII	Enzymatic test (Chromogenic assay)	BIO	B	2	Yes	BSP/QMS	P	Open	Delete
OMCL-AU_TGAL	Assay of human coagulation factor VIII	Enzymatic test (Chromogenic assay)	BIO	C	3	Yes	PTS/QMS	P	Open	Delete

In order to get detailed information about a "competence" record, please click the button "Open" next to the respective record line.

Delete Competences

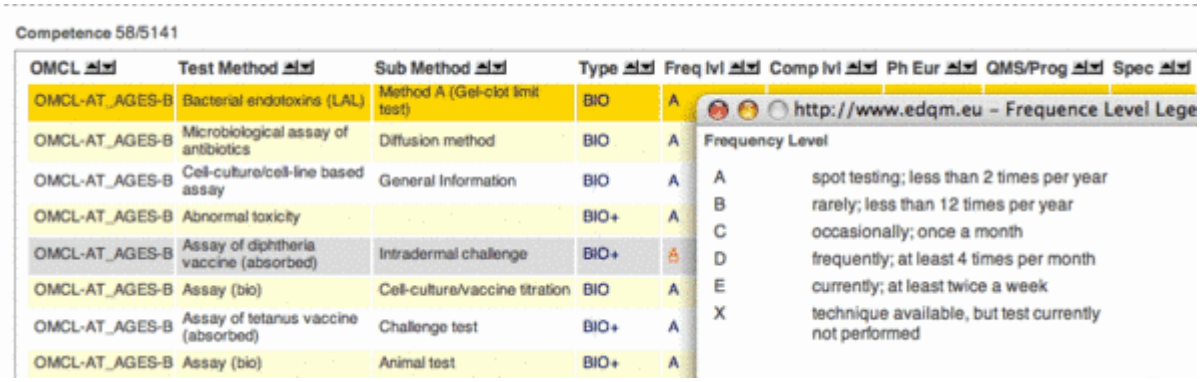
It is only possible to delete those competences, which are allocated to your OMCL (in the example above you see the list of competences from the view-point of a read/write user from the Austrian OMCL AGES-B).

The "Delete" buttons of other OMCLs remain deactivated (grey).

The Competences Domain

Abbreviations used in the Competence List

Some further information concerning the "competence list": You can get information about what stands behind the used abbreviations "BIO", "BIO+", "PC" under Type, "A", "B", "C", "D", "E", "X" under Frequency Level, "0", "1" "2", "3", "4" under Competence Level, and "A", "P", "M" under Specifiers, by clicking on the respective symbols. This will open an extra explanatory window as show exemplarily for "Frequency Level".


Competence 58/5141
OMCL
Test Method
Sub Method
Type
Freq lvl
Comp lvl
Ph Eur
QMS/Prog
Spec
OMCL-AT_AGES-B Bacterial endotoxins (LAL) Method A (Gel-clot limit test) BIO A
OMCL-AT_AGES-B Microbiological assay of antibiotics Diffusion method BIO A
OMCL-AT_AGES-B Cell-culture/cell-line based assay General Information BIO A
OMCL-AT_AGES-B Abnormal toxicity BIO+ A
OMCL-AT_AGES-B Assay of diphtheria vaccine (absorbed) Intradermal challenge BIO+ A
OMCL-AT_AGES-B Assay (bio) Cell-culture/vaccine titration BIO A
OMCL-AT_AGES-B Assay of tetanus vaccine (absorbed) Challenge test BIO+ A
OMCL-AT_AGES-B Assay (bio) Animal test BIO+ A
http://www.edqm.eu - Frequence Level Lege
Frequency Level
A spot testing; less than 2 times per year
B rarely; less than 12 times per year
C occasionally; once a month
D frequently; at least 4 times per month
E currently; at least twice a week
X technique available, but test currently not performed

Below other abbreviations used in the "competences list" are explained.

Type
BIO = Biological method without involvement of animals
BIO+= Biological method with involvement of animals
PC=Physicochemical method

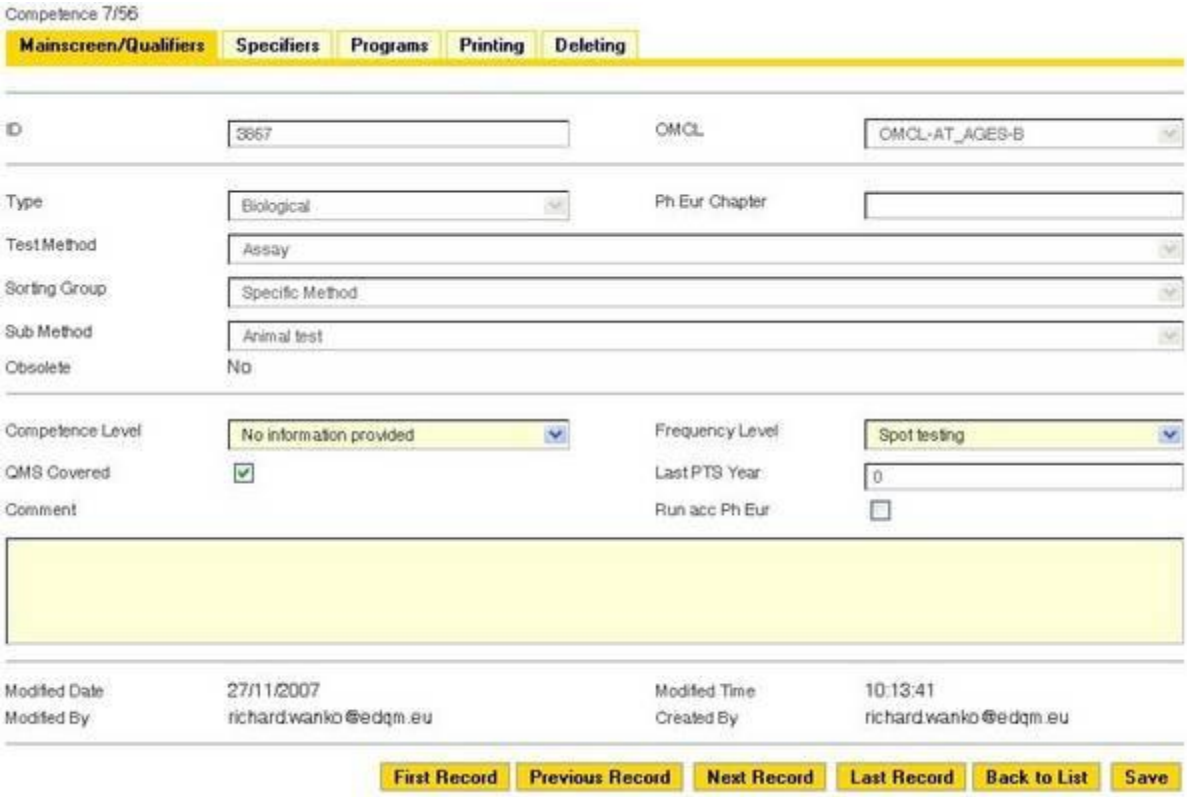
Competence Level
0="No information provided"
1="Able to perform tests using a given technique/method."
2="Able to modify/optimise an existing method."
3="Able to construct new methods."
4="Detailed knowledge of physicochemical and/or biological principles and mechanisms involved in the technique/method."

Specifiers
A="Animal"
P="Product Class"
M="Manufacturer"

The Competences Domain

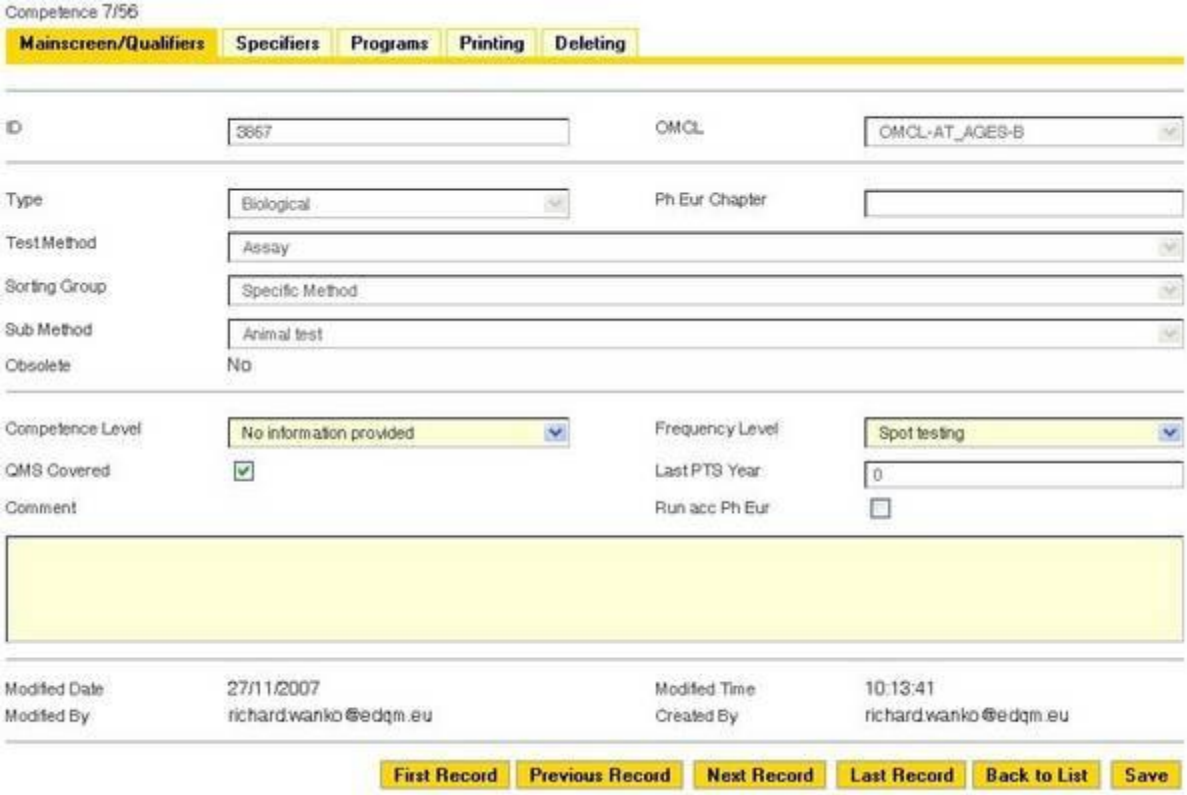
Detailed Records of Competences

An individual competence record includes 5 sub-sections/folders.
After opening you will reach the mainscreen of the competence record. All other folders are visible in the riders' bar, which is located at the top end of the page.



The Competences Domain

Mainscreen/Qualifiers



This folder includes the core test method information and information about the so-called qualifiers (competence level, frequency level, PTS reference, QMS information, Ph.Eur. reference).

Please note: If the box "QMS Covered" is clicked, this indicates, that the respective test method is covered by a QMS system, which has been externally assessed (for definition see chapter OMCL/Lab categories).

By ticking the box "Run acc Ph Eur" you indicate that the method is run according to the European Pharmacopoeia.

The Last PTS Year information is triggered by the entries in the folder "Programs".

The note "Obsolete" is triggered by the EDQM system administrators via the Native Client part. In case a Ph.Eur. method becomes obsolete, this is automatically indicated in the respective competence record.

The Native Client is a part of the database, which is not accessible by OMCL users, where e.g. the content of pop-up menus are defined.

Record Tracking

Record tracking works similar to what is described under "OMCL", see "Information about Modifications".

Accessing Corresponding Competence Folders

The corresponding folders of other competence records of a selected list can be accessed by using the respective buttons located on the bottom end of the screen (similar to the "OMCL" records).

Saving of Competence Records

With respect to saving updated records the same principles apply as described in the "OMCL" domain.
For both, the specifiers "Animal", "Product Class", "Manufacturers" and the programs "MSS", "BSP", "CAP" data are selected from pop-up menus. As soon as an attribute is selected and the button "Add Record" is activated, the data are saved. You do not need to click on the "Save" button on the bottom end of the screen in addition. This is also applicable for "PTS history" data entries.

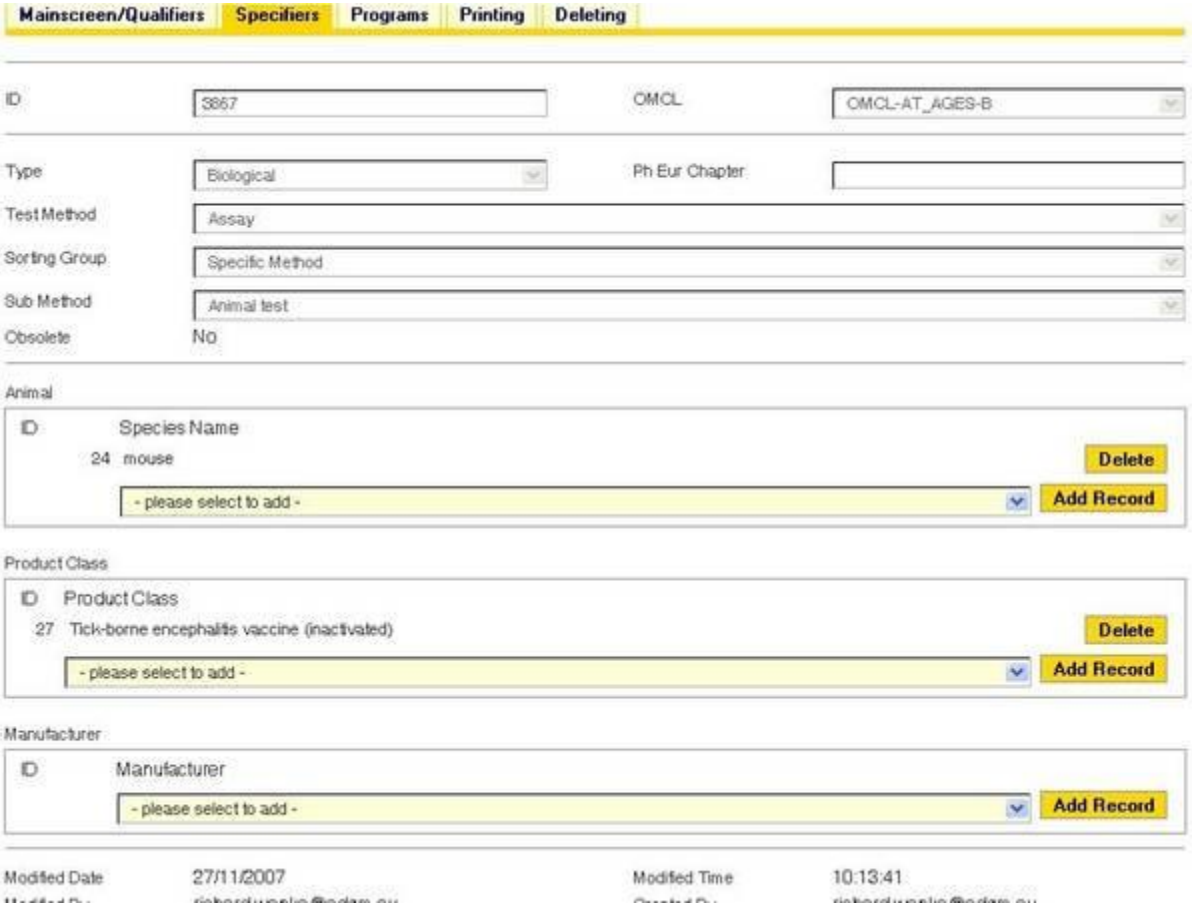
In any other case if changes have been made in a record, the "Save" button needs to be clicked before leaving the sub-section; otherwise the changes get lost.

Indication of Successful Saving

Whenever a "Add record" or "Save" button is activated the successful saving of data is indicated on the upper right hand of the respective folder; this applies not only for the "Competences" domain, but also for "OMCL" and "User".

The Competences Domain

Specifiers



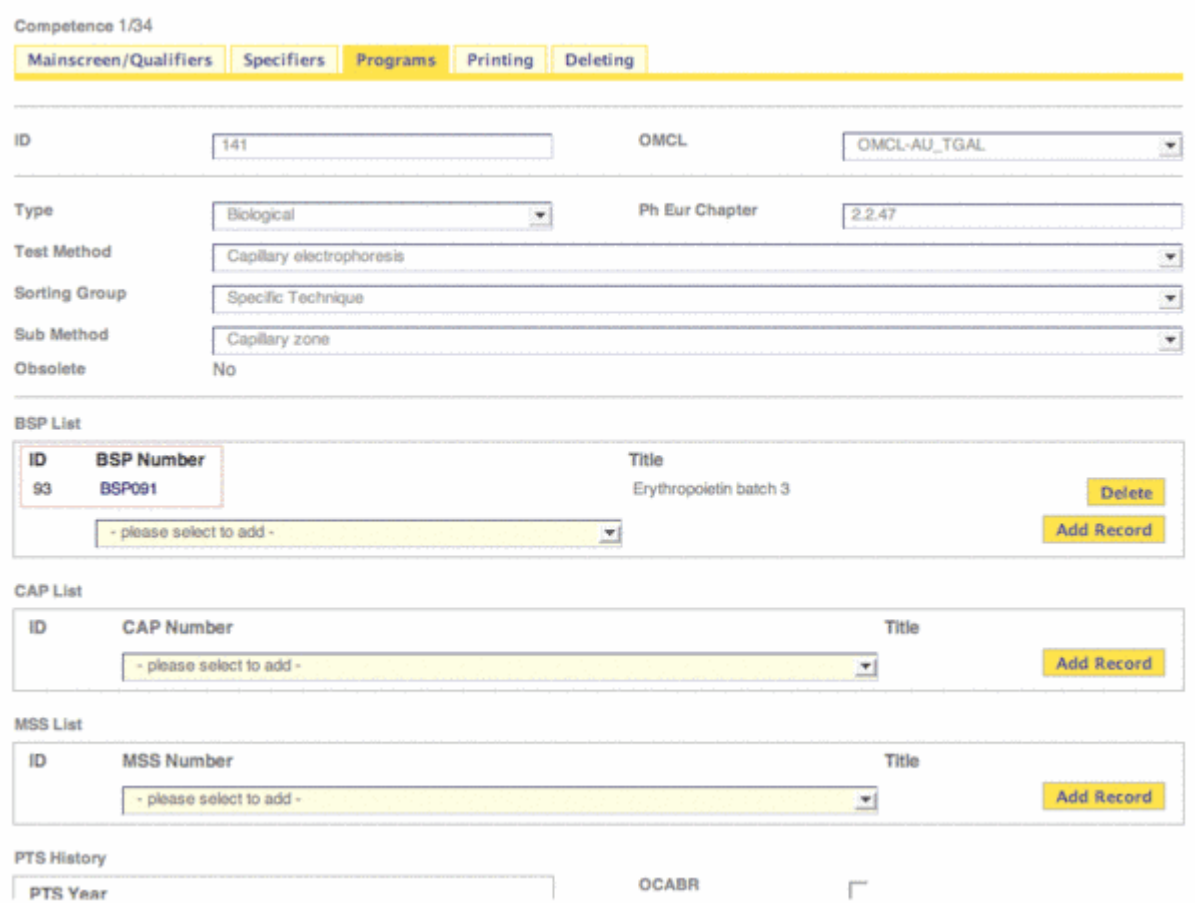
In this sub-section you can make links to "animals", "product classes" and "manufacturer" methods, where applicable.
With respect to product classes preliminary the titles of the vaccine, antitoxin or specific monographs of the Ph.Eur. are used (e.g. Cholera Vaccine).

Please note: "Manufacturer" references should only be made in very particular cases e.g. for vaccines, which are tested in the course of the OCABR program according to a specific method of the manufacturer (e.g. specific immunochemical methods).

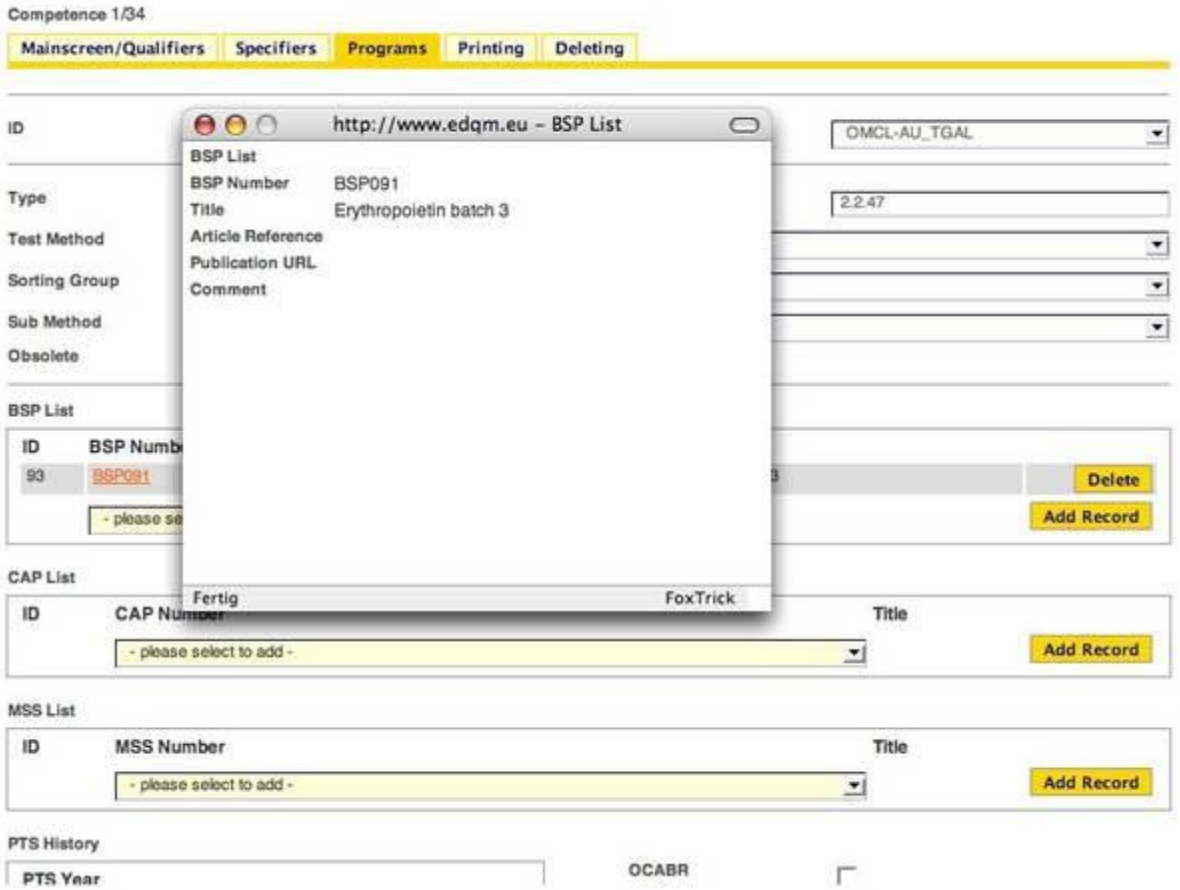
The Competences Domain

Programs

In this sub-section you can link the defined test method/sub method to OMCL Network programs such as PTS, CAP, MSS, BSP and OCABR. In case of BSP, CAP and MSS the corresponding project title is provided.



By clicking directly on a BSP/CAP/MSS reference number (marked in blue), you open a window, which provides you further detailed information about the corresponding project. In case there is an URL quoted you are directly led to the source document, when clicking on the link.

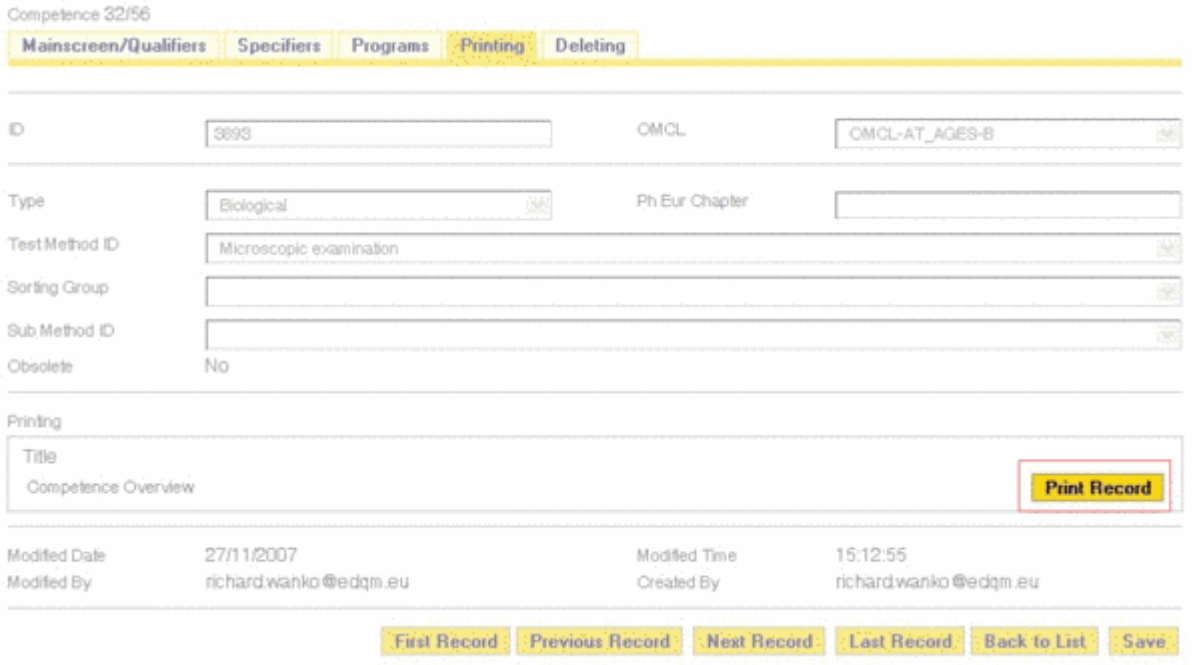


For PTSs, the years of performance are provided, but no reference is made to the project number. This decision was taken for data confidentiality reasons. Also PTSs outside the EDQM program can be recorded.

The Competences Domain

Printing

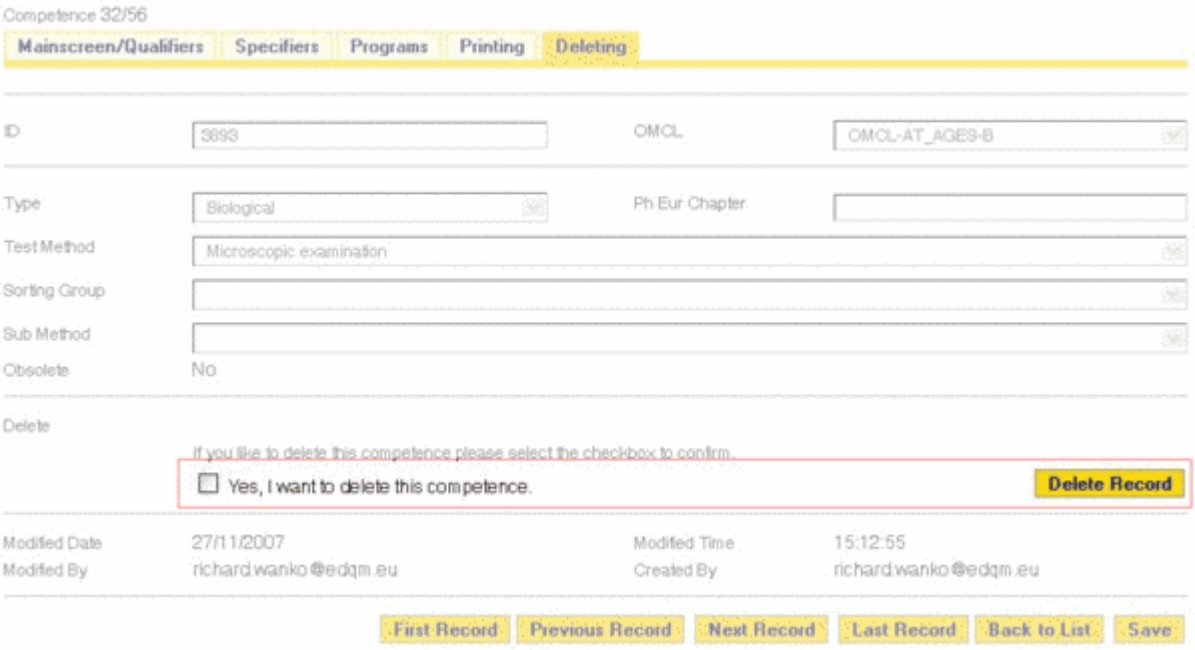
In this sub-folder it is possible to print a standard format including all information related to a specific competence of an OMCL (click on "Print Record" - Competence Overview).



The Competences Domain

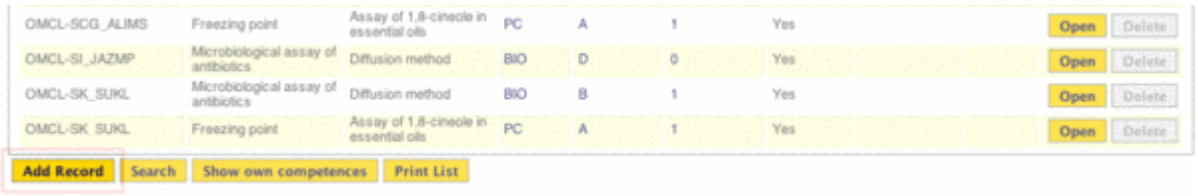
Deleting

This function will allow you to delete a complete competence record (of course only a record, which has been established by your OMCL). Before you can click on the "Delete Record" button, you have to tick the respective box to activate the delete function.



The Competences Domain – add competences

Add Competences
Inserting a New Competence

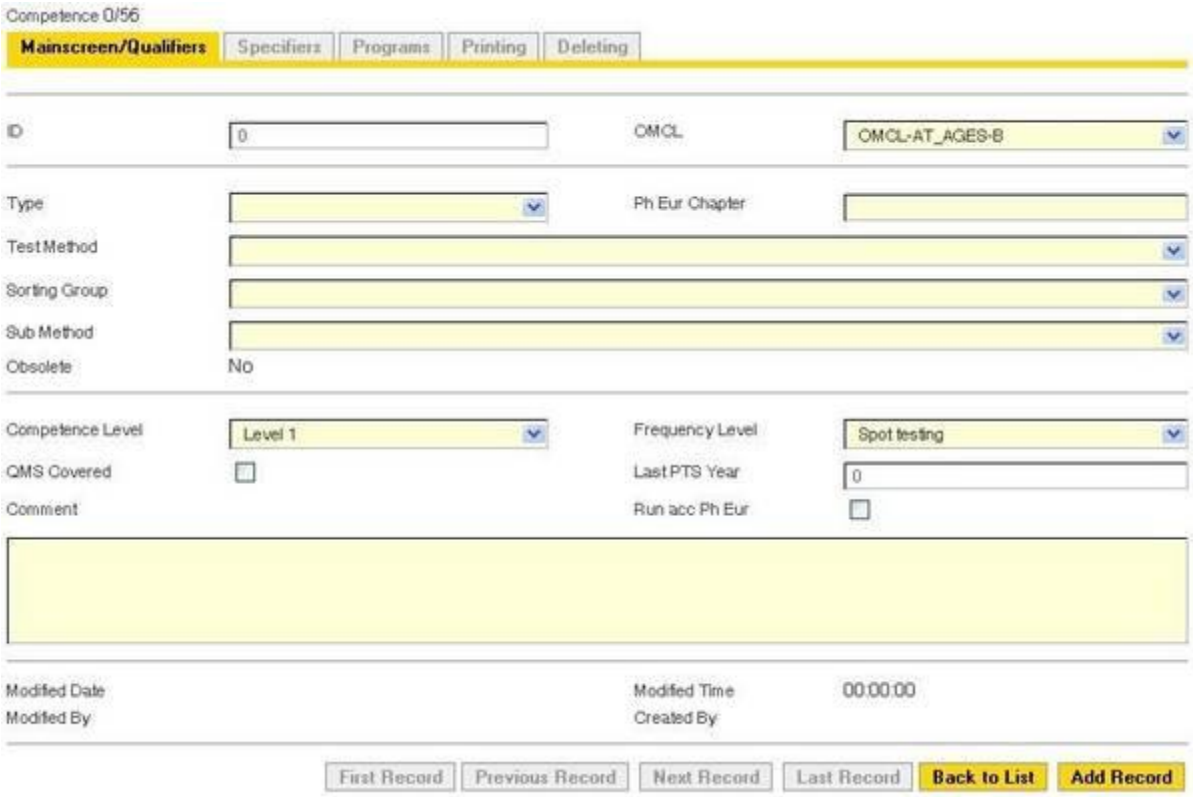


In order to create a new record, please click on the button "Add record", which is located on the bottom end of the "competence list".
You will reach a blank "mainscreen", which allows you to start entering a new record.
The following sub-sites and screens explain the different table elements.

The Competences Domain

Mainscreen Basic Setting

The blank "main-screen" is the starting point for entering a new record.



OMCL Code

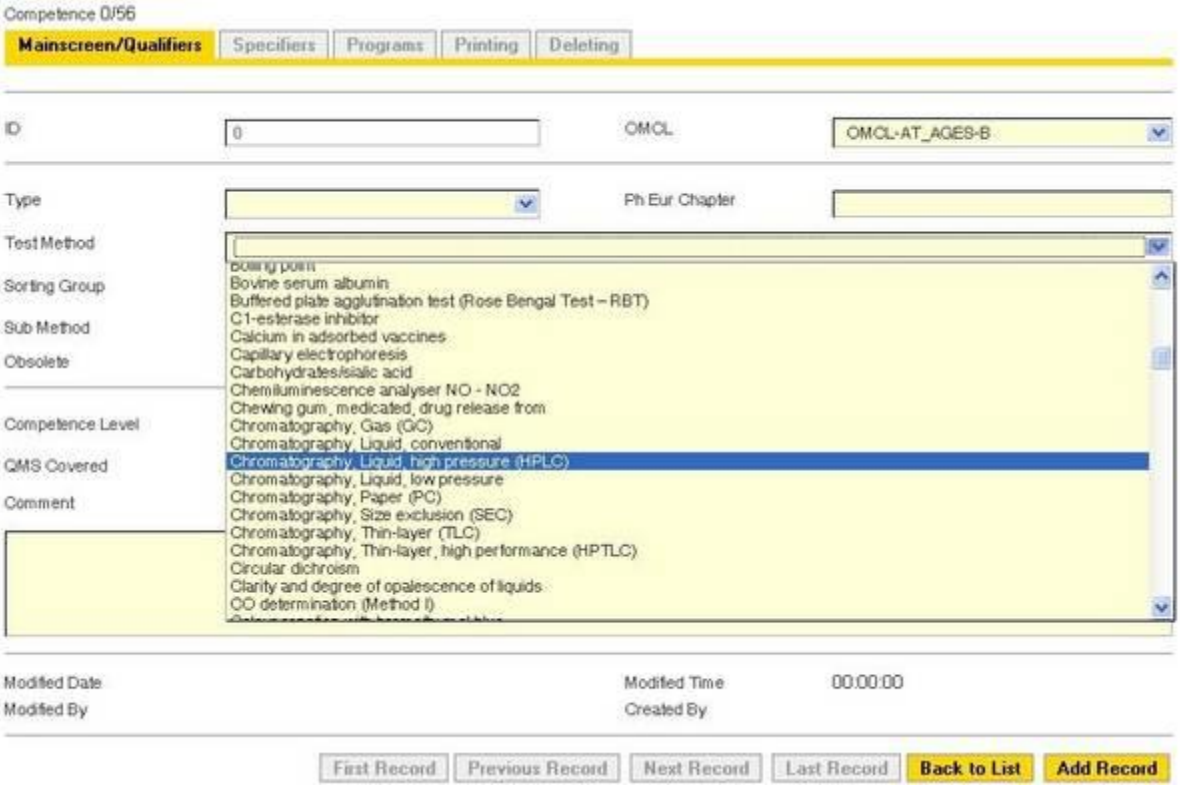
The OMCL code of your OMCL will appear by default in the respective field in the upper right part of the folder. It is not possible to change this code, thus you are not able to add a competence on behalf of another OMCL.

The Competences Domain

Qualifiers
Drop Down - Test Method

You can either keep the field "Type" empty. In that case the pop-up for "Test Method" will display the complete list of all registered test methods in alphabetic order, from which you can select the method.

Please note: This list is maintained by the EDQM administrators via the Native Client domain (back end) and can be enlarged at any time upon request - the same is applicable for any other pop-up lists of the database.

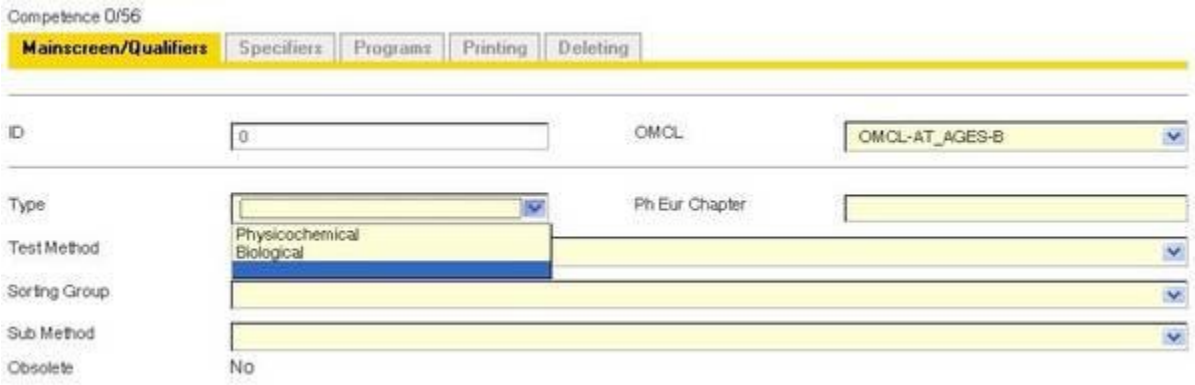


The Competences Domain

Qualifiers
Drop Down - Type

You can shorten the list by pre-selecting under "Type" the attributes:

- Physicochemical
- Biological



The Competences Domain

Qualifiers
Sorting Group

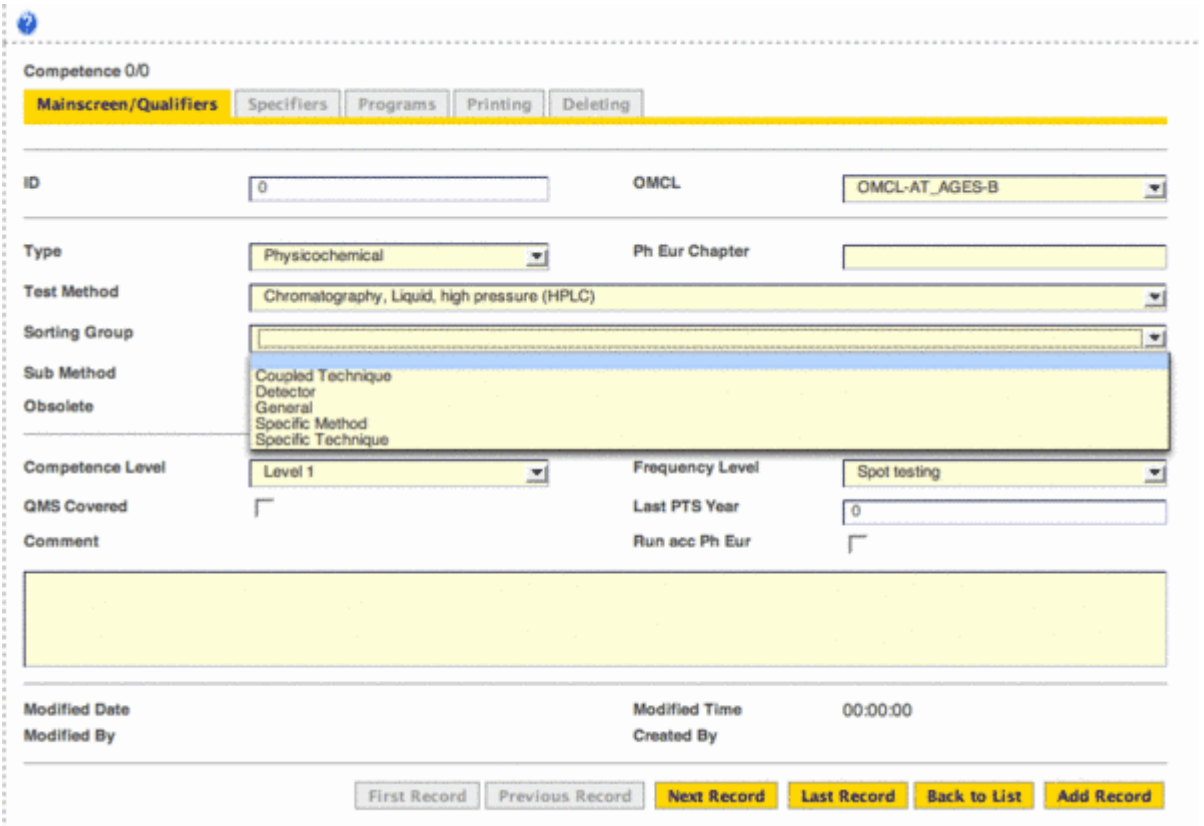
Using Ph.Eur. reference

Provided you know the Ph.Eur. reference number for a general test method, you can alternatively enter this number under "Ph Eur Chapter", and consequently get the corresponding test method.

Please note: The nomenclature of the test method/sub-method follows the convention of the European Pharmacopoeia, wherever applicable. In case the test method and the combination of test method/sub-method have different Ph.Eur. references, the latter overrules the former one.

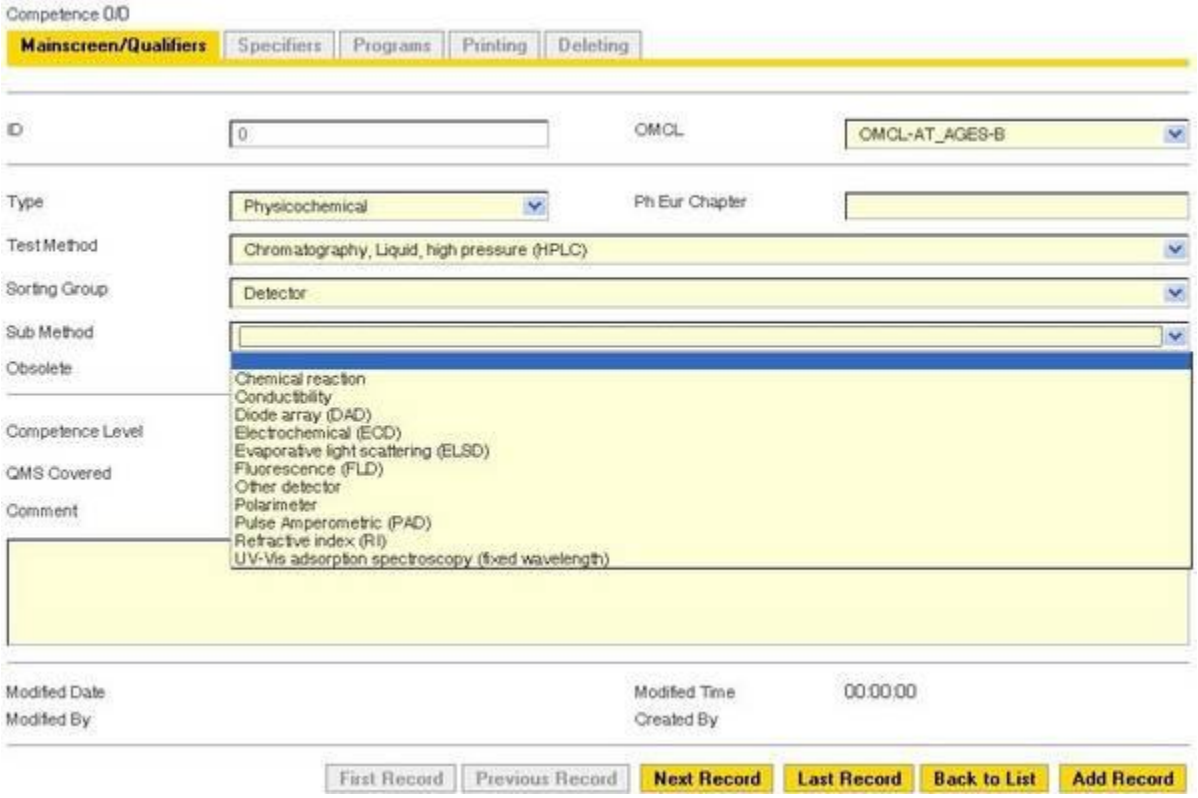
Drop Down - Sorting Group

In the present case you have chosen HPLC as test method. In a next step you may select a "Sorting Group" in order to shorten the list of corresponding sub-methods. For some test methods, different types of sub-methods might be attached. Taking the example of HPLC, this method can be assigned to a specific detector (e.g. DAD), a specific coupled technique (e.g. HPLC-MS), a specific technique (e.g. chiral column) or a specific method (e.g. acetic acid in synthetic peptides).



The Competences Domain

Qualifiers
Drop Down - Sub-Method



In the present example you have selected detector as sorting group and hence come to a list of possible detectors dedicated to HPLC, from which you can now choose the required one.

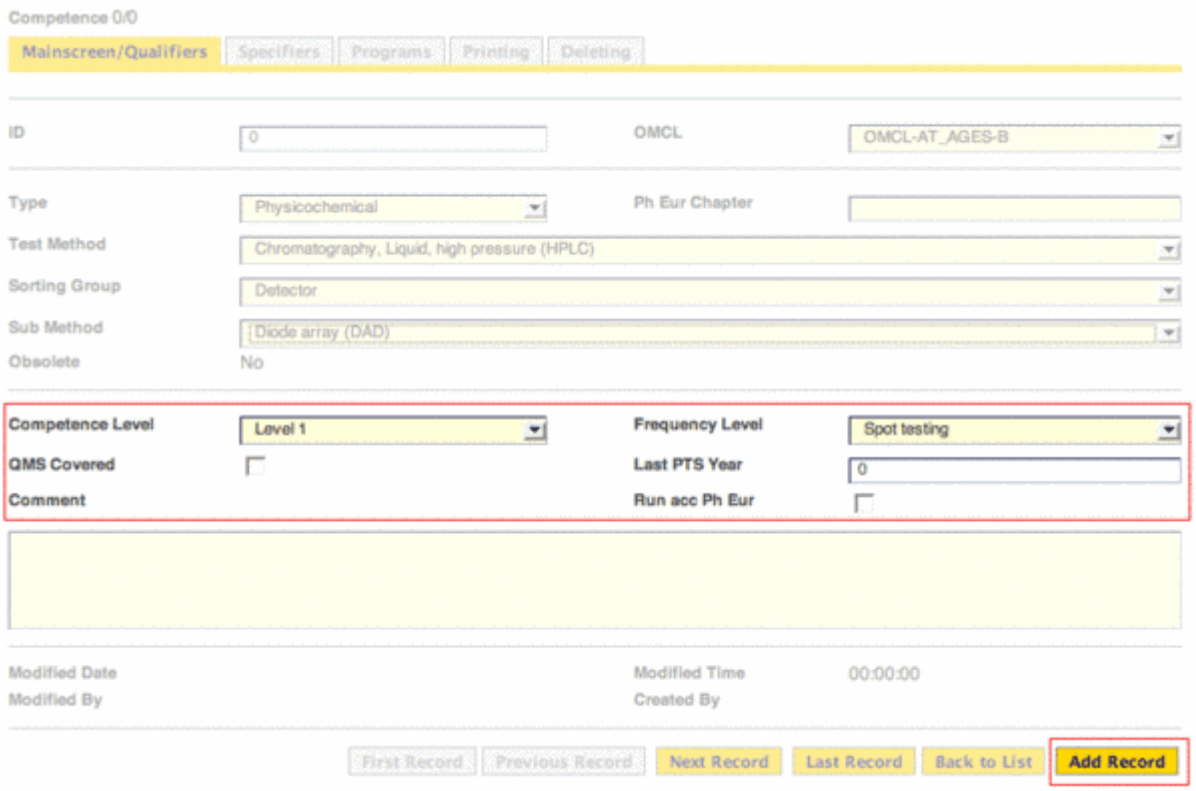
Please note: In case you have not selected a "Sorting Group" the corresponding sub-method list for instance of HPLC will be much longer and more heterogeneous, as all possible attributes are considered.

The Competences Domain

Qualifiers
Levels

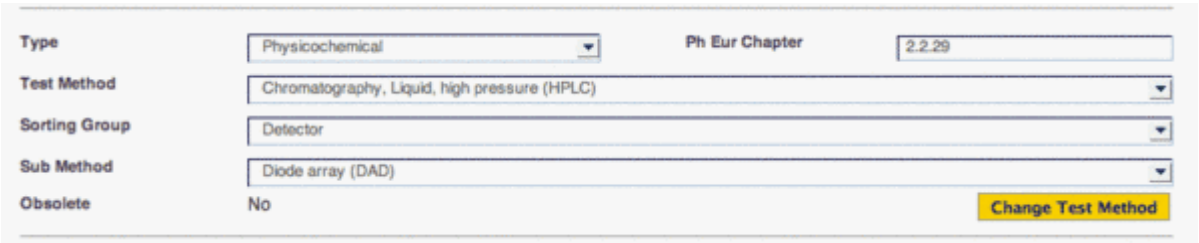
Drop Down - Attribution of Qualifiers

Let's assume you have selected "Diode array (DAD)" as corresponding detector. You can now also define qualifiers by choosing from pop-up lists or by clicking on the respective tick-boxes.



"Freezing" and “Defreezing” of Test-Method / Sub-Method Records

If you finally click on "Add Record" the upper part of the screen including the core test method information turns into grey and is “frozen”. In order to “defreeze” the test method information the button “Change Test Method”, which is located below the “Sub Method” field has to be activated.

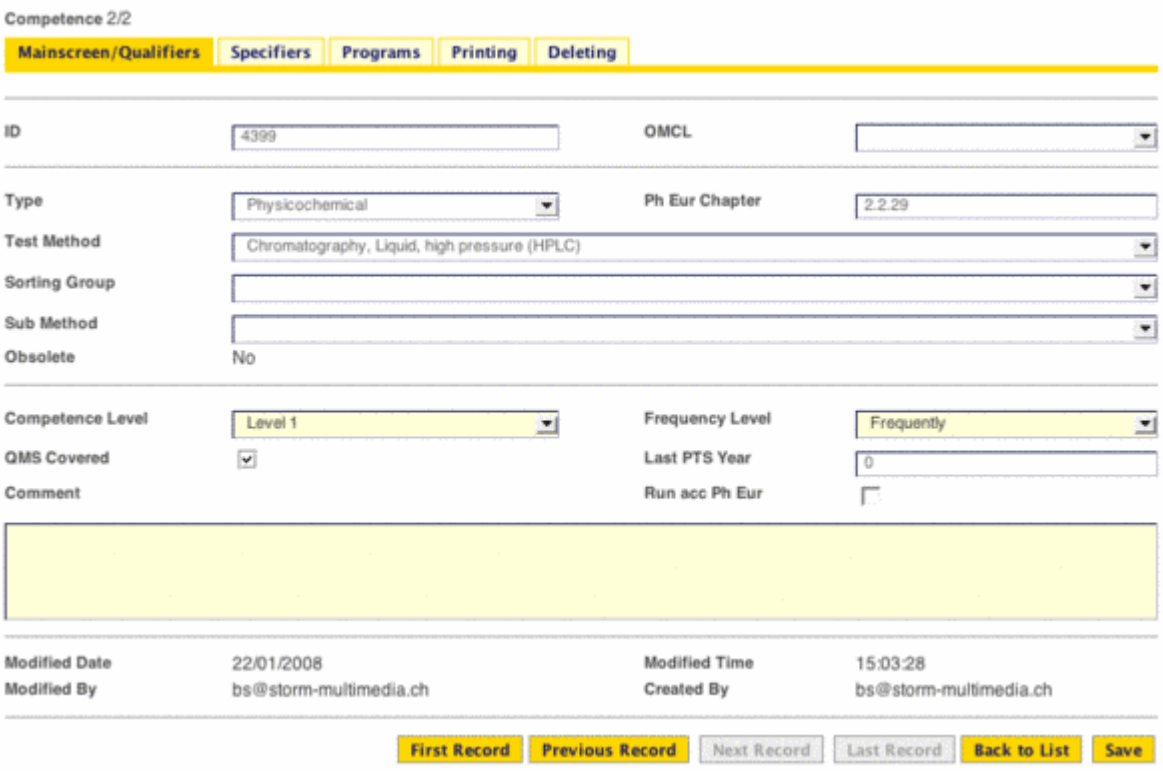


The Competences Domain

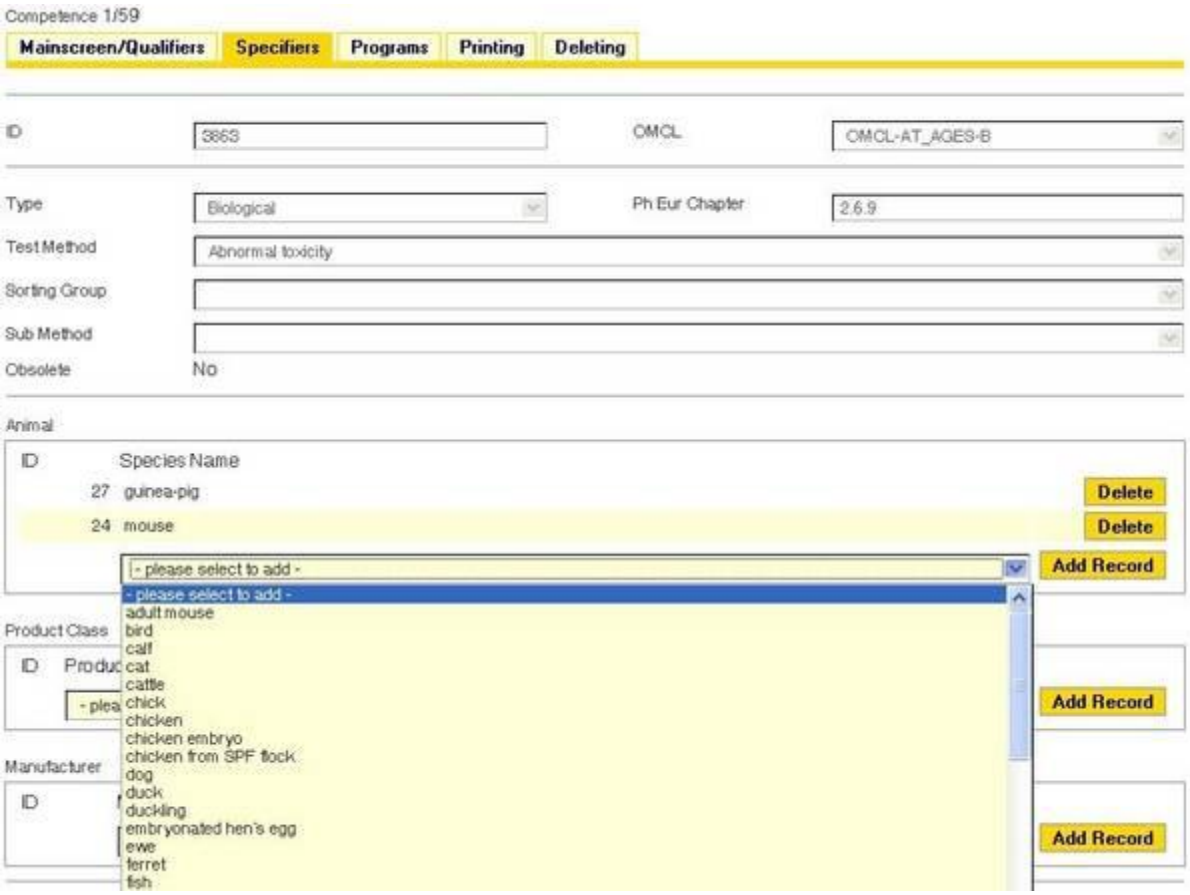
Specifiers / Programs

Attribution of Layer - Specifiers

You can now attribute "specifiers" and "programs" to your test method/sub-method, where relevant, by opening the respective folders, which are now activated; they appear in grey as long as the test method/sub-method is not validated.



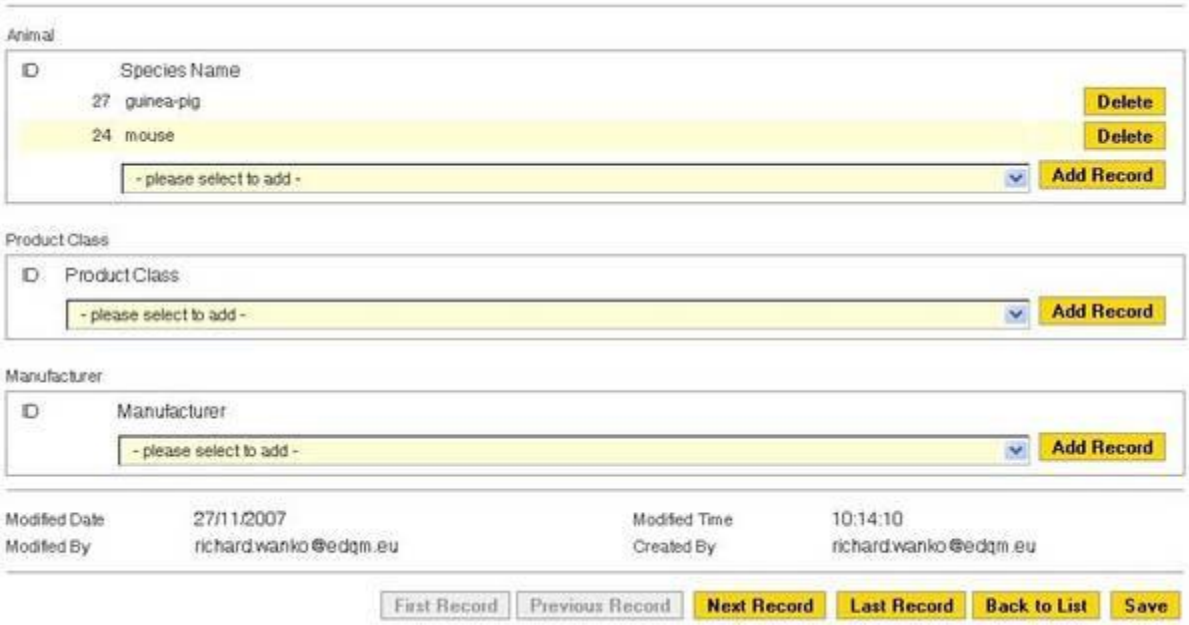
The specifiers "Animal", "Product Class", "Manufacturers" and the programs "MSS", "BSP", "CAP" are selected from pop-up menus.


Competence 1/59
Mainscreen/Qualifiers
Specifiers
Programs
Printing
Deleting
ID
3863
OMCL
OMCL-AT_AGES-B
Type
Biological
Ph Eur Chapter
2.6.9
Test Method
Abnormal toxicity
Sorting Group
Sub Method
Obsolete
No
Animal
ID
Species Name
27 guinea-pig
Delete
24 mouse
Delete
- please select to add -
Add Record
- please select to add -
adult mouse
bird
calf
cat
cattle
chick
chicken
chicken embryo
chicken from SPF flock
dog
duck
duckling
embryonated hen's egg
ewe
ferret
fish
Product Class
ID
Add Record
Manufacturer
ID
Add Record

The Competences Domain

Deletion of an Attribute

With the allocation of a specifier/program there also appears a "Delete" button in the respective line, which allows the authorised user to delete the attribute again, if necessary.



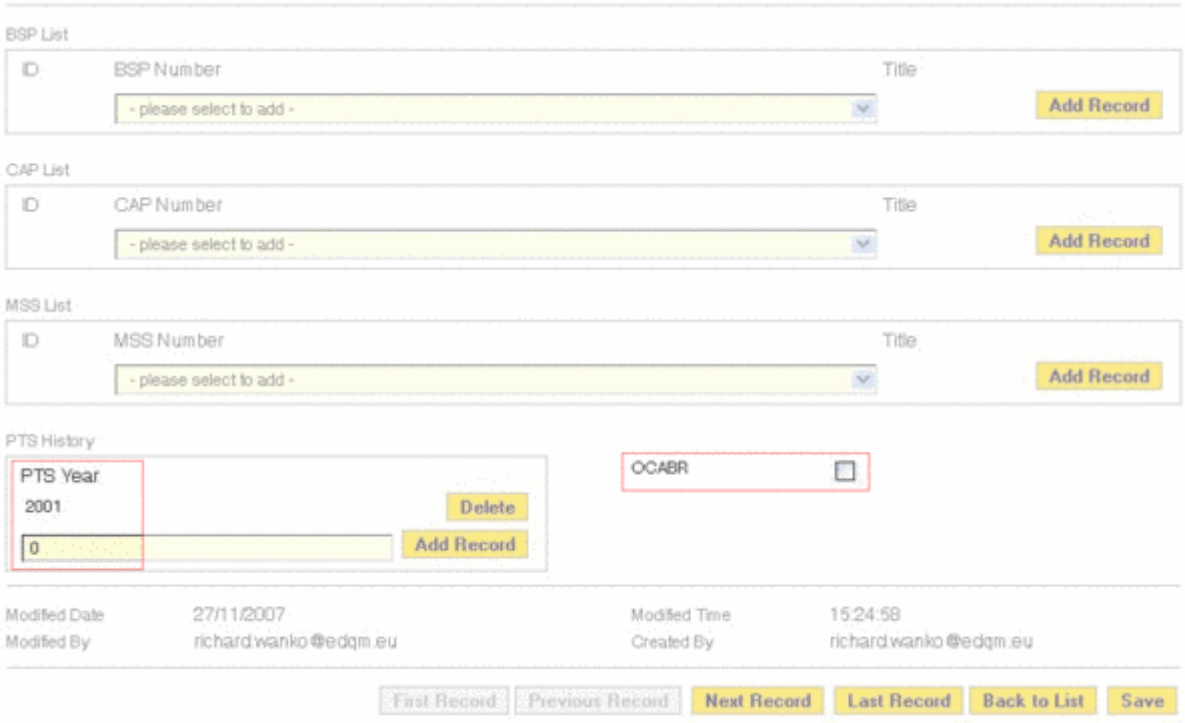
The Competences Domain

Specifiers: PTS / OCABR

PTS History / OCABR Information

The same principle also applies to the PTS history (located under program), with the only difference, that data input is not handled via a pop-up menu, but manually. The years of performance of a PTS are added to the record cumulatively.

If methods are involved in OCABR activities, a tick-box has to be activated.



The User Domain

Providing New Accounts

OMCL administrators are allowed to provide new user accounts within their organisation.

Specific Searches within User Domain

When clicking on "User" a search dialogue box opens, which is only useful in case you have a lot of users registered within your organisation. In that case you can search for the last name or the login = email address (wild card search). This search function is more relevant for the EDQM system administrators, as EDQM can query the list of all users registered in the database.

The User Domain

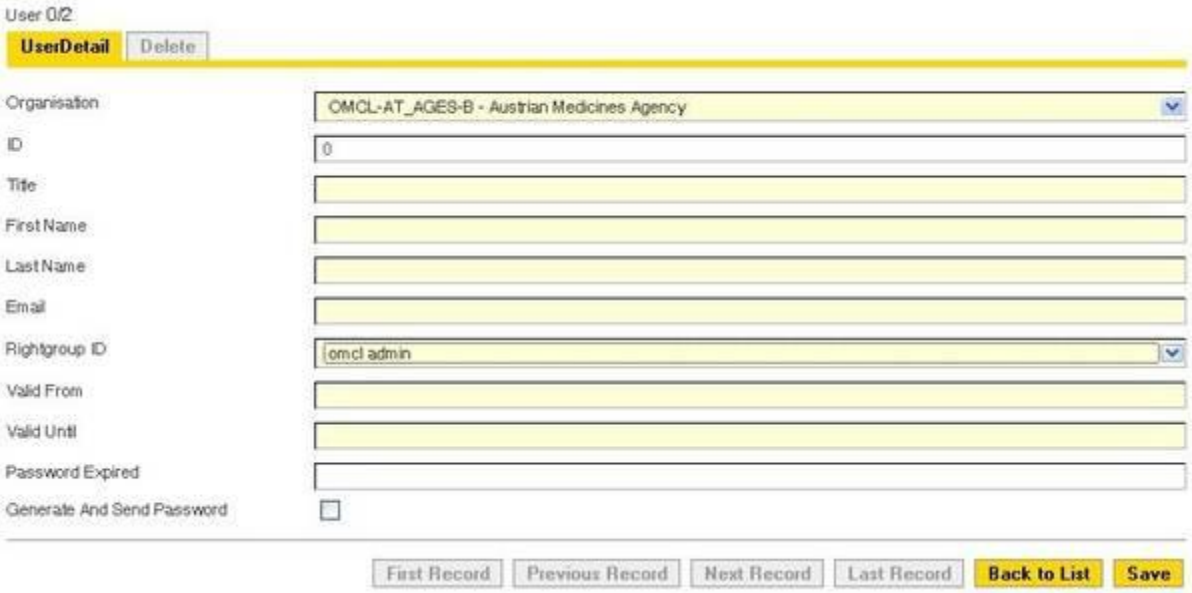
"Show All" Function

By clicking on "Show All" (or alternatively by clicking on "Search" while leaving the search boxes empty) you receive the list of users allocated to your OMCL. In the given example there are 2 users registered.

The User Domain

Adding a New User

If you want to add a new user to the list, click on "Add record" which will open a window, where you can now start entering all necessary information of the user. For example, as OMCL administrator of the Austrian OMCL AGES-B you can only allocate new users to this organisation.

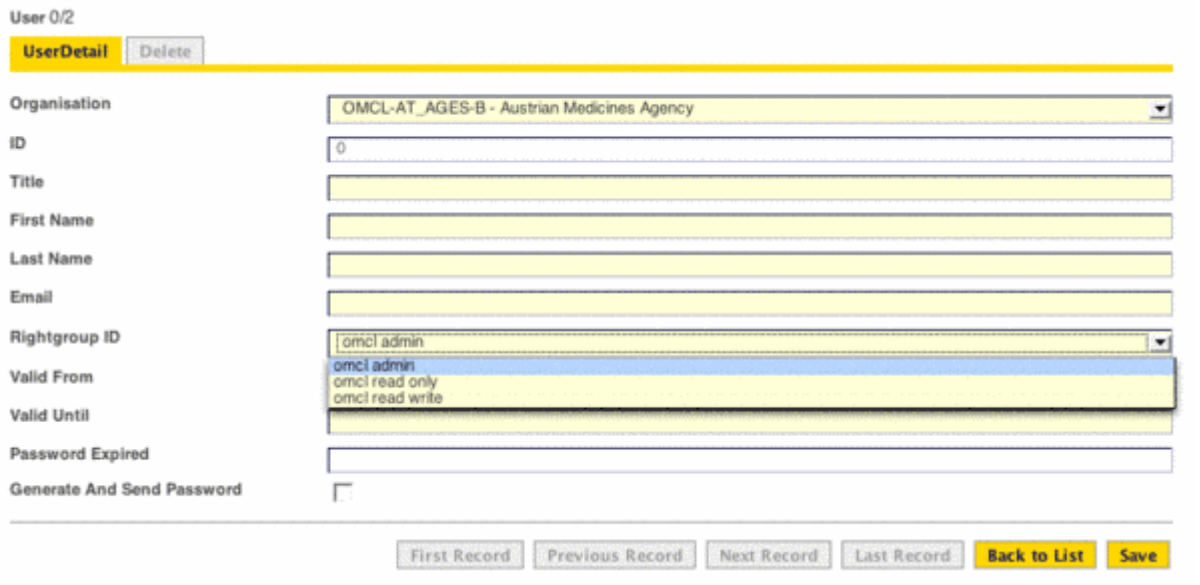


The User Domain

Access Levels

User Access Levels

There are three levels of OMCL access rights, which you can provide: "OMCL admin", "OMCL read only" and "OMCL read/write". It should be stressed that the system allows to provide the access right "OMCL admin" to more that one user within an organisation.



Username / Password

The email address, which you enter into the corresponding field, will be at the same time the username of the new user. For that reason you should always use personal email addresses and no "collective addresses". The email address you enter is case insensitive whichever convention you use (capital or small letters) the password will be recognised by the system as username. The system will not allow you to enter a new user record without defining an email address already at this stage.

Validity of Access

You can also define a start date "Valid From" and end date "Valid Until" for limiting the access to the database. If this option is kept open the date of creation of the record (by activating the "Save" button) will be taken as "Valid From" date and the "Valid Until" date will remain empty.

Password Policy

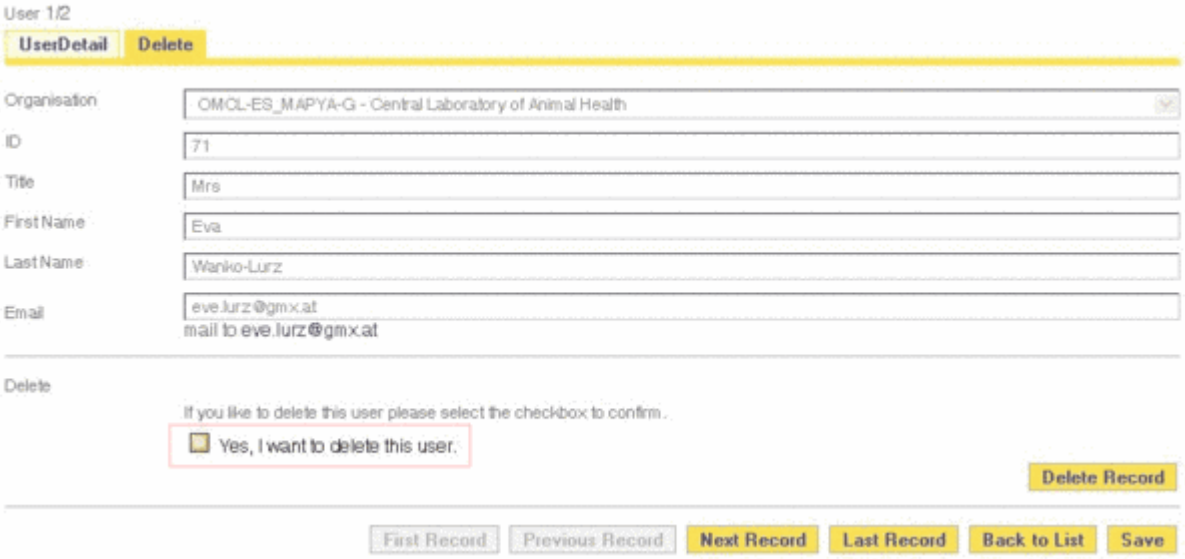
Finally when activating the tick-box "Generate And Send Password" followed by clicking on the "Save" button, an automatic email will be sent to the email address of the new user informing him/her about the password. At the same time the "Password Expired" field shows the date, when the password was delivered. This is the trigger, which forces the new user, when first entering the database with the received password to change it immediately. Please note that no fixed time frame is defined within which the new user has for the first time to enter the database and change the password. Nevertheless all passwords will expire after one year. As soon as the password has been changed the date of next password expiry will be shown in the respective field. After the expiry date of the password the user will be asked automatically to rename his/her password the next time he/she tries to access the database.

Please note: OMCL administrators will never know the password of the users, for whom they have created an account. The same is also applicable for the system administrators at EDQM.
It is not possible to allocate a user to more than one organisation; e.g. an OMCL user (defined by the email address) from the Austrian OMCL can only get read/write access to either AGES-B or AGES-C, but not to both at the same time. This should be considered when organising the database maintenance within the OMCLs, respectively when defining a OMCL record.

The User Domain

Deleting User Records

As OMCL administrator you can delete a user record within you organisation by clicking on the respective button. It is even possible for an OMCL administrator to delete another OMCL administrator, if necessary. A window will open, which will ask you to confirm by activating on the respective box, if you really want to delete the record (similar approach as e.g. for deletion of an own competence record).



Finally it should be noted, that you are not authorised to delete your own record. You can activate the delete button, but in that case the following message will appear: "You can't delete your own record". With this principle it is not possible to delete by mistake all user records of an OMCL; at least one OMCL administrator account always remains per OMCL.

General features in the OMCL / Competences / User domain

The General functions are applicable for the three domains "OMCL", "Competences" and "User".
An overview is given by the sitemap below:

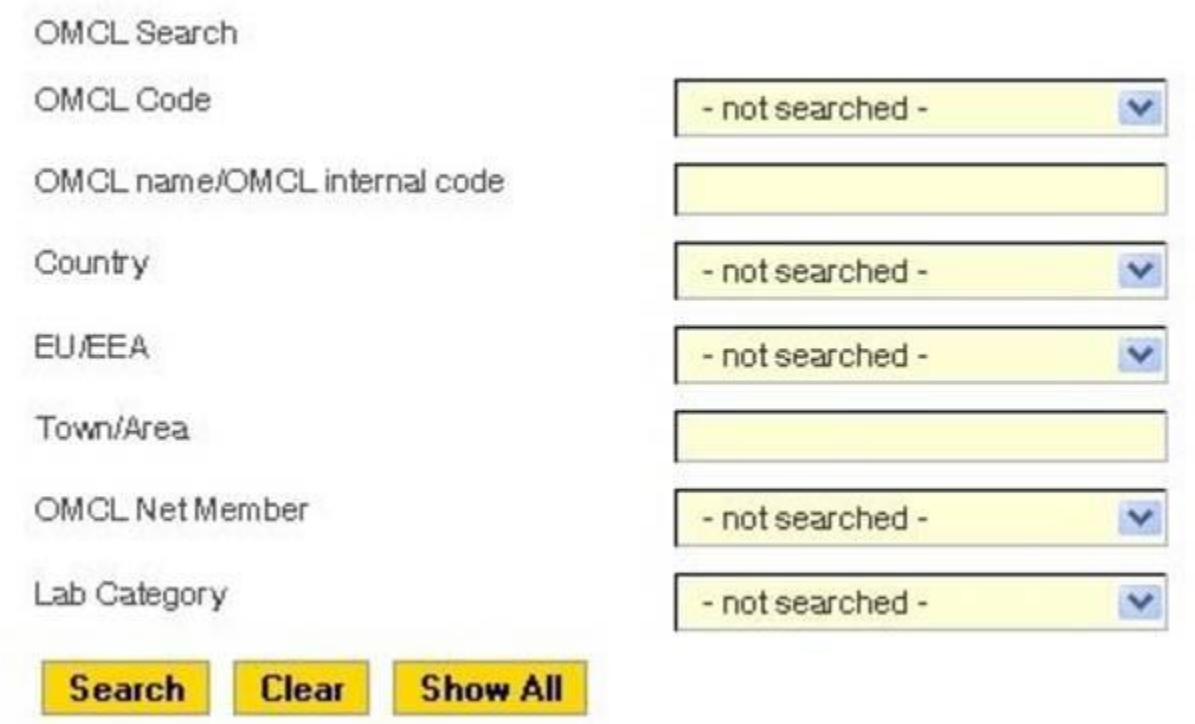
Search

Activating a Search (Search Button)

In order to initiate a search the "Search" button has to be activated.

Clearing a Search (Clear Button)

You can delete all search options simply by clicking the "Clear" button or by deleting them manually step-by-step.



General features in the OMCL / Competences / User domain

Sorting of Lists

The OMCL, Competences and User lists can be selected in ascending or descending alphabetic order by clicking on the respective arrows next to the column titles. In the upper left corner you get information about the number of records available within this domain.

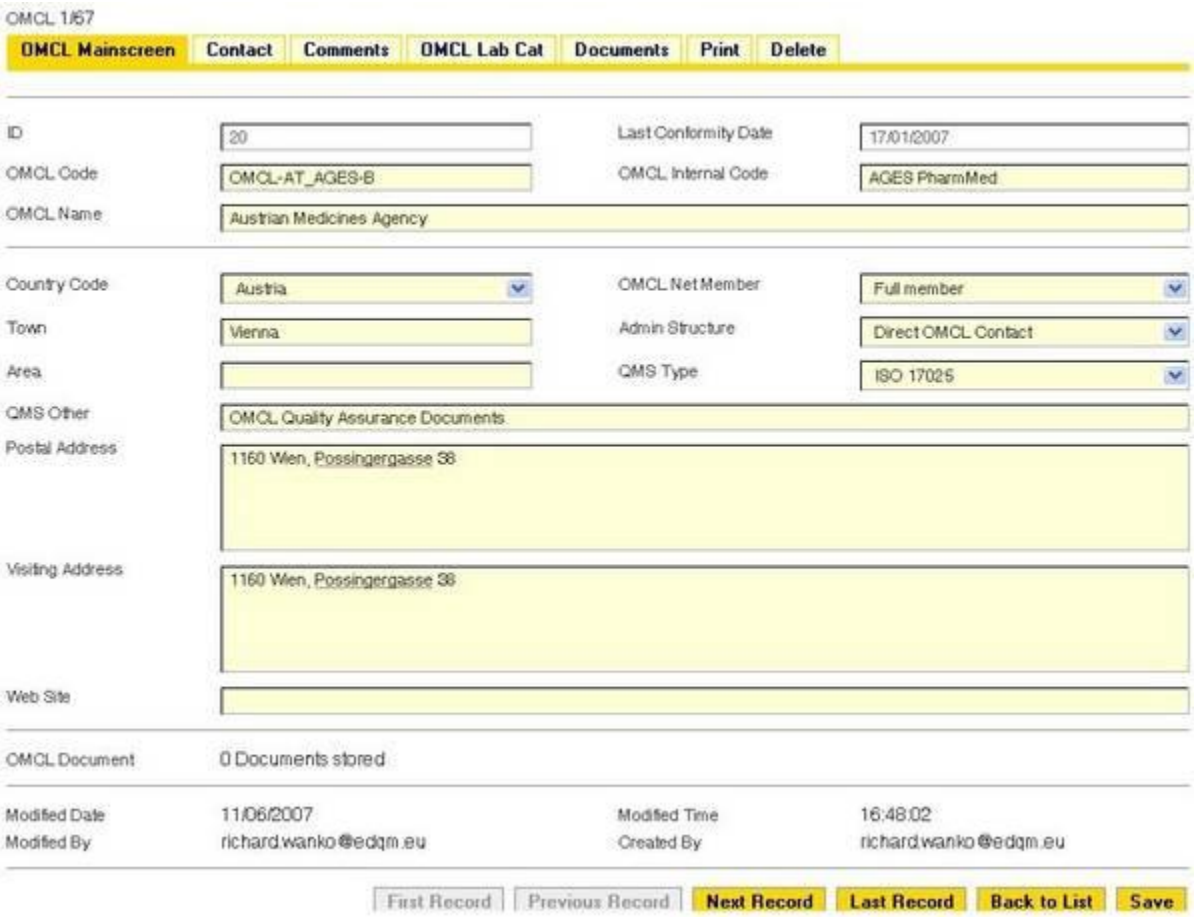
OMCL 67/67

OMCL Code	OMCL Name	Country	Town	OMCL Net Member	
OMCL-AT_AGES-B	Austrian Medicines Agency	Austria	Vienna	Full member	Open
OMCL-AT_AGES-C	Austrian Medicines Agency	Austria	Vienna	Full member	Open
OMCL-AU_TGAL	Therapeutic Goods Administration Laboratories	Australia	Canberra	Associated	Open
OMCL-BA_IMQC	Institute for Medicines Quality Control	Bosnia Herzogovina	Sarajevo	Full member	Open
OMCL-BE_IPH-B	Scientific Institute Public Health – Section Biological Standardisation	Belgium	Brussels	Full member	Open
OMCL-BE_IPH-C	Scientific Institute of Public Health, Medicines Section	Belgium	Brussels	Full member	Open
OMCL-BE_VAR	Veterinary and Agrochemical Research Center	Belgium	Ukkel	Full member	Open
OMCL-BG_BDA	Bulgarian Drug Agency	Bulgaria	Sofia	Full member	Open
OMCL-BG_ICVP	National Veterinary Service, Institute for Control of Veterinary Medicinal Produ	Bulgaria	Sofia	Full member	Open
OMCL-CA_BGTD	Biologics and Genetic Therapies Directorate	Canada	Ottawa	Associated	Open

General features in the OMCL / Competences / User domain

Saving Information

Please note: In case you switch between folders within the OMCL or Competences domain all data, which have been added or changed in the folder you have just left, will get lost, if you forget to click on the "Save" button. This is not applicable for information added, modified or deleted with an "Add record" / "Edit record" and "Delete" button.



Indication of Saving Status

Whenever an "Add record" or "Save" button is activated the successful saving of data (or its failure) is indicated on the upper right hand of the respective folder; this applies to the "OMCL", "Competences" and "User" domains.

General features in the OMCL / Competences / User domain

Records

"Back to List" Button

In order to go back from the detailed folders to the list, please use the "Back to List" button.

Switching between Records

On the bottom end of each screen in the OMCL, Competences and User domains you find buttons, which allow you to switch between different records from a selected list. You can switch between the corresponding folders of each record by using the "First Record", "Previous Record", "Next Record" and "Last Record" button.

Information of Modification (Record Tracking)

You will find at the bottom end of each folder in the OMCL, Competences and User domains information about the last data modification date, the last modification time and an identifier (email address) of the person, who created the complete record and who modified existing data within a record the last time.

Position of Record

In the upper left corner of the screen you find information about the position of the record within the respective domain. In the example given below you are under domain OMCL in the first out of 67 OMCL records in the folder "OMCL Mainscreen". This applies for the domains "OMCL", "Competences" and "Users".

Detail Sitemap - OMCL Online Manual

- HOME
- OMCL
- COMPETENCES
- USER
- LOGOUT
- HELP
  - Online Help
    - Database Access
      - Username / Password
      - Password Change
      - Password Errors
      - Logout
    - Navigation
    - OMCL Domain
      - Search Functions
      - Deletion of Records
      - Records Structure
      - Saving / Modifying
      - Mainscreen
      - Contact
      - Comments
      - OMCL Lab Cat
      - Documents
      - Print
      - Delete
    - Competences Domain
      - General Search Fields
      - Combined Search Fields
      - Overview
      - Abbreviations
      - Detailed Records
        - Mainscreen / Qualifiers
        - Specifiers
        - Programs
        - Printing
        - Deleting
      - Add Competence
        - Mainscreen Basic Setting
        - Qualifiers: Test Method
        - Qualifiers: Type
        - Qualifiers: Sorting Group
        - Qualifiers: Sub-Method
        - Qualifiers: Levels
        - Specifiers / Programs
        - Deletion of Attributes
        - Specifiers: PTS / OCABR
    - User Domain
      - Show All / Search
      - Add User
      - Access Levels
      - Delete User
    - General Features
      - Search
      - Sorting of Lists
      - Saving Information
      - Records
    - Sitemap